ALCOHOLIC BEVERAGE REGULATION ADMINISTRATION
ALCOHOLIC BEVERAGE CONTROL BOARD

NOTICE OF PROPOSED RULEMAKING

The Alcoholic Beverage Control Board (Board), pursuant to the authority set forth in D.C. Official Code §§ 25-211(b), 25-798 (2006 Supp.) and Mayor's Order 2001-96 (June 28, 2001) as revised by Mayor's Order 2001-102 (July 23, 2001), hereby gives notice of the intent to adopt the following proposed rules that would create a new section 718 of Title 23 of the District of Columbia Municipal Regulations ("DCMR") to establish procedures for the recently created pilot subsidy program for reimbursable details. The Alcoholic Beverage Regulation Administration's (ABRA) FY 2008 budget transfers $1,000,000 to the ABRA fund balance to subsidize this program. These procedures are necessary to establish guidelines for the distribution of subsidies by ABRA to the Metropolitan Police Department (MPD) to cover costs incurred by Alcoholic Beverage Control licensees (licensees) for MPD officers working reimbursable details.

Pursuant to D.C. Official Code § 25-211(b)(2) (2001), these proposed rules are also being transmitted to the Council of the District of Columbia, for a ninety (90) day period of review. The proposed rules will become effective in not less than thirty (30) days from publication of this notice in the D.C. Register, or upon approval by the Council by resolution, whichever occurs later. If the Council does not approve or disapprove the proposed rules by resolution, in whole or in part, within the ninety (90) day review period, the proposed rules shall be deemed disapproved.

Title 23 DCMR is amended by adding a new section 718 to read as follows:

718 REIMBURSABLE DETAIL SUBSIDY PROGRAM

718.1 This section sets forth the procedures for receiving reimbursement from ABRA under the subsidy program for monies paid to the Metropolitan Police Department (MPD) by licensees for the hiring of MPD officers to work a reimbursable detail. This section shall apply only to the extent that: (1) the Council funds the subsidy program, and (2) ABRA has sufficient funds earmarked for this program remaining to reimburse MPD for costs incurred by licensees for MPD officers working reimbursable details.

718.2 ABRA will reimburse MPD thirty percent (30%) of the total cost of invoices submitted by MPD to cover the costs incurred by licensees in FY 2008 for MPD officers working reimbursable details. MPD shall submit to ABRA on a monthly basis invoices documenting the thirty percent (30%) amount owed by each licensee. Invoices will be paid by ABRA to MPD within thirty (30) days of receipt in the order that they are received until the subsidy program's funds are depleted.

718.3 ABRA shall notify MPD when funds in the subsidy program fall below two hundred and fifty thousand dollars ($250,000).

718.4 Any invoices unpaid by ABRA either for good cause or a lack of sufficient funds left in the subsidy program shall remain the responsibility of the licensee.

718.5 ABRA shall not be involved in determining the number of MPD Officers needed to work a reimbursable detail which shall remain the responsibility of MPD.

Copies of the proposed rulemaking can be obtained by contacting Fred Moosally, General Counsel, Alcoholic Beverage Regulation Administration, 941 North Capitol Street, N.E., 7th Floor, Washington, D.C. 20002. All persons desiring to comment on the proposed rulemaking must submit their written comments, not later than thirty (30) days after the date of the publication of this notice in the D.C. Register, to the above address.

DEPARTMENT OF CONSUMER AND REGULATORY AFFAIRS

NOTICE OF PROPOSED RULEMAKING

The Director of the Department of Consumer and Regulatory Affairs, pursuant to authority set forth in § 316 of the Condominium Act of 1976 ("Act") effective March 8, 1991 (D.C. Law 8-233; D.C. Official Code § 42-1903.16) (2001), and Mayor's Order 2002-166 dated September 21, 2002, hereby gives notice of intent to adopt the following amendments to Title 14 of the District of Columbia Municipal Regulations (DCMR) in not less than forty-five (45) days from their publication in the *D.C. Register*. The proposed rules provide for the Condominium Declarant's warranty against Structural Defects. These rules also include the term of the warranty, the amount of Security to be posted by the Declarant, the form of the Security to be posted, and term of the Security to be posted.

These proposed rules shall be submitted to the Council of the District of Columbia ("Council") for a 45-day period of review, excluding Saturdays, Sundays, legal holidays, and days of Council recess. These rules shall become effective upon Council approval, or forty-five (45) days after submission, if the Council has not disapproved the proposed rulemaking, and on publication of the final rules in the *D.C. Register*.

Title 14 DCMR (Housing) (July 1991) is amended as follows:

A new subtitle H is added to read as follows:

Subtitle H: Condominium Conversion

A new Chapter 72 is added to read as follows:

CHAPTER 72 CONDOMINIUM DECLARANT'S WARRANTY AGAINST STRUCTURAL DEFECTS

Section

7200 TERMS OF RESIDENTIAL WARRANTY

7200.1 A Declarant shall warrant against Structural Defects for a first time Conveyance to a bona fide Purchaser of a Condominium Unit. The Declarant warrants against Structural Defects in each Condominium Unit for a two (2) year period. The two (2) year warranty period for each Unit begins on the date of the Conveyance to a bona fide Purchaser.

7200.2 The Declarant shall warrant against Structural Defects in the Common Elements of the Condominium for a two (2) year period. The two (2) year warranty period for the Common Elements, or any portion thereof, shall begin on the date that portion of the structure or building has been completed or the date of occurrence of any of the following, whichever is later:

(a) Within any additional land or portion thereof that does not contain a Unit, at the time the additional land is added to the Condominium;

(b) Within any Convertible land or portion thereof that does not contain a Unit, at the time the Convertible land may no longer be converted;

(c) Within any additional land or Convertible land or portion of either that does contain a Unit, at the time the first Unit therein is first conveyed to a bona fide Purchaser; or

(d) Within any other portion of the Condominium, at the time the first Unit is conveyed to a bona fide Purchaser.

7201.3 The Declarant of a Conversion Condominium may offer the Units, Common Elements or both in "as-is" condition. If the Unit is conveyed in "as-is" condition, the Structural Defect warranty is limited to defects in components installed by the Declarant or work done by the Declarant unless the Declarant gives the Unit Owner a more extensive written warranty.

7201 SECURITY FOR RESIDENTIAL UNIT WARRANTY TO BE POSTED BY THE DECLARANT

7201.1 The Declarant shall provide the Agency with a Security Interest to establish the warranty. The warranty shall be established before the first Conveyance of a residential Unit to a Purchaser. The form or type of the Security Interest is set out in section 7202 and it shall satisfy costs arising from the Declarant's obligation under this chapter.

7201.2 The Declarant shall notify the Agency, in writing, upon the first Conveyance of a residential Unit to a bona fide Purchaser.

7201.3 The amount of Security to be posted by the Declarant shall be equal to ten percent (10%) of all estimated Construction or Conversion Costs.

7201.4 If the construction or conversion is a mixed-use Condominium or the residential Condominium component of a mixed-use project, then the Construction or Conversion Costs of the Declarant for which Security must be provided shall be limited to those costs allocated to the construction or conversion of the residential portion of a mixed-use Condominium, or the residential Condominium component of a mixed-use project. The estimated Construction and Conversion Costs of the Condominium should include the residential Condominium Unit's pro rata share of the Common Elements, based on the residential Condominium Unit's percentage interest in the Common Elements.

7201.5 The Declarant shall provide the total Construction or Conversion Costs with the application for Condominium registration submitted to the Agency:

(a) Construction or Conversion Cost estimates shall be based upon a reasonable estimate of the scope of the project and information provided in the Registration Package;

(b) The Declarant shall provide the actual costs of construction and conversion if available at the time the Registration Package is submitted; and

(c) Upon completion of construction the Declarant shall amend the Registration Package to reflect the actual costs of the project.

7201.6 The Declarant shall certify the known Construction or Conversion Costs and estimate the remaining Construction or Conversion Costs in an affidavit to be submitted to the Agency on or before the Conveyance of the first Unit and the posting of the Security.

7201.7 Acceptance of the affidavit or the Security tendered shall not be deemed a determination by the Agency that the amount of Security to be posted meets the requirements of this chapter.

7201.8 Declarant shall file an updated certification every six (6) months after the date of initially posting the Security, until all construction at the project is completed:

(a) If the estimated or actual total Construction or Conversion Costs increases by ten percent (10%) or more from the amount set forth in the affidavit first filed with the Agency, the certification must reflect the increase and the Declarant shall post additional Security with the Agency in the amount of ten percent (10%) of the increase in total Construction or Conversion Costs; and

(b) The Declarant shall provide the additional Security to the Agency within ten (10) days of filing the updated certification.

7201.9 Any Owner may challenge the adequacy of the Security posted by the Declarant by written notice to the Agency.

7201.10 The Director shall provide written notification to the Declarant if any warranty Security provision is not satisfied:

(a) Violations of the warranty regulations constitute a default;

(b) The Agency shall notify the Declarant of the default by certified mail, registered mail or through personal service to the Declarant or its agent;

(c) The Declarant is required to cure the default within ten (10) business days; and

(d) In the event of a default, the Agency may exercise its authority to take all legal measures to obtain compliance.

7202 FORMS OF SECURITY

7202.1 The Declarant may post the required Security in the form of a Letter of Credit, a Bond or, a Lien against Declarant's equity in unsold Units in the Condominium or such other form of Security as may be approved by the Agency.

7202.2 The language of the instrument establishing the Security Interest shall be approved in advance by the Agency. Approval of the language of the instrument shall not be deemed a determination by the Director as to the sufficiency of the amount of Security posted or whether that Security has been posted for the appropriate term.

7202.3 Security in the form of a Letter of Credit shall:

(a) Be an irrevocable standby letter of credit;

(b) Drawn at sight issued by a financial institution that;

i. Is licensed to conduct business in the District of Columbia;

ii. Maintains an office or branch location within the District of Columbia; and

iii. Is insured by the federal government.

(c) Name the Mayor or his designee as the beneficiary;

(d) Be established as of the date of the Condominium registration application or Condominium registration, whichever is later; and

(e) Be automatically extended until two (2) years after the sale of the final Condominium Unit. See the appendix of forms for the Letter of Credit form.

7202.4 Security in the form of a Bond shall:

(a) Be issued by a financial institution that:

i. Is licensed to conduct business in the District of Columbia;

ii. Maintains an office or branch location within the District of Columbia; and

iii. Is insured by the federal government; and

(b) Name the Mayor or his designee as the beneficiary;

(c) Be established as of the date of Condominium registration application or Condominium registration, whichever is later; and

(d) Automatically extend until two (2) years after the sale of the final Condominium Unit. See the appendix of forms for the Bond form.

7202.5 Security in the form of a Lien against the Declarant's equity in unsold Units in the Condominium is acceptable only in the Agency's discretion:

(a) The Declarant shall submit proposed drafts of the Security documents for the Agency's review and approval;

(b) The Declarant must provide evidence of the valuation of the proposed property demonstrating that the Declarant holds equity totaling at least ninety percent (90%) of the current listed sales price of the Units, or if not listed, then the current listed sales price of comparable Units in the Condominium;

(c) The Declarant must provide and pay the premium for a title insurance policy naming the Mayor or his designee as the insured; and

(d) The Lien shall be:

i. In the form of an agreement secured by recordable deed of trust or recordable mortgage, including foreclosure powers in the event of default, in favor of the Mayor or his designee;

ii. In first priority position; and

iii. Recorded among the land records of the Office of the Recorder of Deeds. The Declarant shall provide the original assignment to the Director.

7202.6 The Declarant shall provide the original Letter of Credit, Bond or Lien instruments and any and all original amendments, where applicable, to the Director.

7202.7 In the event that the original Letter of Credit or Bond or any amendments thereto cannot be located, the Declarant shall obtain and deliver to the Agency a substitute original from the issuing financial institution.

7202.8 The Letter of Credit or Bond shall contain a provision obligating the financial institution upon request of the Declarant or the Director to issue a substitute original of the Letter of Credit or Bond or any amendments. Upon the Director's request, the Declarant shall provide a revised Letter of Credit or Bond.

7202.9 The Director shall receive up to the face amount of the Letter of Credit or Bond upon presentation.

7202.10 The Letter of Credit or Bond shall be maintained by the District of Columbia or, if applicable, pursuant to a final order or judgment.

7202.11 Unless otherwise agreed upon, the Letter of Credit or Bond shall be honored upon presentation according to the standard and practices of the financial institution upon which the instrument was drawn but in no event more than seven (7) business days after presentation. These rules apply equally to the original or substitute original instrument.

7202.12 Any disputes arising from the Letter of Credit, Bond or Lien shall be determined pursuant to District of Columbia law.

7203 TERMS OF THE POSTED SECURITY

7203.1 The posted Security shall be for a two year period, in accordance with section 7200.

7203.2 The Declarant may request a reduction in the Security beginning two (2) years after the Conveyance of the first Unit:

(a) The Declarant may request a reduction in the amount of the Security once every six (6) months after the initial two (2) year period;

(b) The amount of Security shall be reduced in pro rata segments;

(c) The reduction(s) shall be based on the percentage interest in the residential portion of the Condominium of those residential Units first conveyed to a bona fide Purchaser(s) more than two (2) years prior to the request; and

(d) In no event shall the Security be reduced below fifty percent (50%) of the original amount of the Security until one year after transfer of control of the residential executive board of the Unit Owners association to the purchasing residential Unit Owners other than the Declarant.

7203.3 The Declarant may treat unsold residential Units as resale Units and be relieved of the Security requirements set forth in this chapter, provided five (5) years have passed since the Conveyance of the first residential Unit to a Purchaser and provided at least one (1) year has passed following transfer of control of the residential executive board to purchasing residential Unit Owners other than the Declarant.

7203.4 Security shall be automatically extended beyond its initial two year term, expiring two years after the sale of the final Unit:

(a) Declarant shall periodically extend whatever form of Security is posted so that adequate Security is consistently in place throughout the period set forth in § 316(b) of the Act (D.C. Official Code § 42-1903.16)(b)) and in these regulations;

(b) Declarant shall provide proof of such extensions to the Director no later than sixty (60) days prior to the expiration of the Security Interest; and

(c) If the Declarant fails to extend such Security as required, the Agency shall take whatever actions are necessary to draw upon the Declarant's Letter of Credit, or liquidate whatever other Security has been posted by the Declarant at least thirty (30) days prior to the premature expiration of the Security Interest.

7203.5 If Claim(s) for Structural Defects filed pursuant to § 316 of the Act (D.C. Official Code § 42-1903.16) are pending at the time any Security posted would otherwise no longer be required, the Declarant is required to maintain the Security in an amount not less than the amount of the total value of outstanding Claim(s). The Security will be maintained until all Claims have been finally resolved and the Security has been made available to satisfy the Declarant's responsibilities.

7204 WARRANTY CLAIM PROCEDURES

7204.1 Notice to the Owner or the Declarant, or response thereto, required of any party under this section shall be in writing and delivered by certified mail, return receipt requested. A copy shall be delivered to:

(a) The Declarant's irrevocable agent designated under § 403 of the Act (D.C. Official Code § 42-1904.03); and

(b) The issuer of the Security for the Warranty.

7204.2 An Owner shall issue notice of a Claim to the Agency and the Declarant which shall include:

(a) Written notification to the Director by an Owner claiming that Declarant is in violation of § 316 of the Act (D.C. Official Code § 42-1903.16) or any of provision of this chapter;

(b) A detailed report from a structural engineer licensed by and qualified to do business in the District of Columbia which identifies the nature and extent of each Structural Defect and a statement whether the identified Structural Defect threatens the safety of residents of the condominium;

(c) Three (3) written cost estimates including the scope of work needed to repair or replace the Structural Defect, from contractors bonded and licensed to conduct business in the District of Columbia; and

(d) Proof of payment for the structural engineer's report.

7204.3 The Claim must be submitted to the Agency during the applicable two (2) year warranty period. Upon receipt, the Agency shall review the Claim to:

(a) Determine whether valid warranty Security exists;

(b) Determine the terms of the Security; and

(c) Assess the timeliness of the Claim filing.

7204.4 The Agency may within ten (10) business days certify that the Claim meets the requirements set out in section 7204.2, and has been timely filed within the applicable two year warranty period for the specific Structural Defect. The Claim is perfected upon satisfaction of sections 7204.2 and 7204.3(c) requirements. Certification under this section shall state that the Agency has made no determination on the merits of the Claim.

7204. 5 Upon Claim certification, the Agency shall issue a notice of filing of a certified Structural Defect Claim to the Declarant, with a copy delivered, return receipt requested, to the Owner including a complete copy of the certified Claim. The Agency shall also notify the Security issuer of the pending certified Claim.

7204. 6 The Declarant shall respond to the Agency's notice of filing of a certified Claim and to the Owner in writing within twenty calendar (20) days after the date of receipt of the Agency's notice. If the Declarant agrees to repair or replace the identified Structural Defect, the Declarant shall complete the repair or replacement of the Structural Defect:

(a) Within seven (7) days after the date of receipt of the Agency's notice if the Structural Defect threatens the safety of residents of the Condominium, or

(b) Within twenty (20) days after the date of receipt of the Agency's notice if the Structural Defect does not threaten the safety of residents of the Condominium, or such additional time as may be granted pursuant to section 7204.7.

7204.7 If the Declarant is unable to complete the repair or replacement pursuant to section 7204.6 the Declarant shall submit a written request for extension of time to the Agency with a copy to the Owner on or before the last day of the twenty (20) day response period:

(a) The Agency may grant the request for good cause;

(b) Good cause may include;

i. The short-term unavailability of labor or materials;

ii. Adverse weather conditions; or

iii. That the nature of the Structural Defect requires more time to repair or replace; and

(c) The Agency shall determine the amount of additional time needed to complete the repair or replacement on a case-by-case basis.

7204.8 Upon completion of the repair or replacement, including under additional time provided under section 7204.7, the Declarant shall notify the Agency in writing with a copy to the Owner, that the repair or replacement of the Structural Defect has been completed.

7204.9. Upon receiving notice of completion, the Agency shall:

(a) Notify the Department of Consumer and Regulatory Affairs which shall inspect the repairs to ensure compliance with applicable building codes; and

(b) After receiving notification from the Department of Consumer and Regulatory Affairs that the repairs or replacements comply with applicable building codes, provide written notice to the Owner and the Declarant stating whether the Structural Defect has been properly repaired or replaced within thirty (30) business days of receipt of the written notice of completion.

7204.10 If after receiving notification from the Department of Consumer and Regulatory Affairs that the Structural Defect has not been properly repaired or replaced, the Agency may:

(a) Allow the Declarant additional time for good cause under section 7204.7 to repair or replace the Structural Defect: or

(b) Draw down on the Security for the warranty under the procedures set forth in section 7204.12.

7204.11 If the Declarant disagrees with the Claim and submits a written objection pursuant to section 7204.6 or fails to file a written response to the Agency's Claim certification, the Agency shall, within forty-five (45) business days:

(a) Assess the merits of all submitted Structural Defect reports;

(b) Conduct appropriate on-site inspections at its discretion;

(c) Prepare findings; and

(d) Provide written notice of its findings to the Declarant and the Owner.

7204.12 If the Agency determines the existence of Structural Defect(s), the Agency may draw down the Security for the repair or replacement of such Structural Defect(s) if the Agency finds, after conducting its own assessment of a certified Claim, that a Structural Defect exists and that:

(a) The Declarant failed to properly repair or replace the Structural Defect; or

(b) The Declarant failed to respond to the Claim pursuant to section 7204.6, or as such time may have been extended pursuant to section 7204.7.

7204.13 The Agency shall apply the appropriate amount of Security funds for repair or replacement of the Structural Defect(s) after conducting its own Claim assessment and reviewing the three (3) estimates from contractors licensed by the District of Columbia submitted by the Owner pursuant to section 7204.2(c).

7204.14 Upon receipt of the Security funds, the Agency shall forward payment directly to the contractor who performed or will perform the repair or replacement work, for the sole purpose of repairing or replacing Structural Defects.

7204.15 Within forty-five (45) days after the end of the two (2) year warranty period, the Agency shall release the remaining Security funds provided that there are no unresolved Claims with respect to the subject Condominium filed within the applicable two year warranty period pending with the Mayor or in a court of competent jurisdiction.

7204.16 The Owner shall notify the Mayor of the filing and outcome of any Claims in a court of competent jurisdiction.

7204.17 Any Owner or Declarant who is aggrieved by the Agency's findings under this section may seek judicial relief in the Superior Court for the District of Columbia.

7205 MAINTENANCE NOT WARRANTED

7205.1 Nothing in this chapter shall be construed to make the Declarant responsible for any items of maintenance relating to the Units or Common Elements. Any Claims for maintenance items shall be denied by the Agency pursuant to § 316 of the Act (D.C. Official Code § 42-1903.16).

7206 SECURITY INTEREST RECORDS

7206.1 The Director shall establish and maintain an internal system to monitor, track and control the Security instruments. At a minimum, this system shall maintain the following information:

(a) Name and address of the Condominium;

(b) Declarant's name, address and telephone number;

(c) Date of delivery of the Security instrument to the Agency;

(d) Security's expiration date;

(e) Amount of the Security;

(f) Security extension date(s); and

(g) Claim information, including but not limited to alleged deficiencies and payment history.

7207 CONVERSION NOTIFICATION

7207.1 The Agency shall forward, as appropriate, a copy of the Letter of Registration, as well as information regarding the Construction or Conversion Costs, the number of Units, and the number of parking spaces to the following governmental entities:

(a) Office of Tax and Revenue;

(b) Office of the Surveyor;

(c) Office of the Recorder of Deeds;

(d) Department of Consumer and Regulatory Affairs;

(e) Office of the Zoning Administrator;

(f) Office of Permitting; and

(g) Any other agency as designated by the Director.

7208 COMPLIANCE & ENFORCEMENT

7208.1 Whenever necessary to ensure compliance with § 316 of the Act (D.C. Official Code § 42-1903.16) or the requirements of these regulations, the Agency may draw upon the Declarant's Security or liquidate whatever Security has been posted by the Declarant.

7208.2 In addition to the penalties set forth in D.C. Official Code § 42-1904.17, civil penalties, fines and sanctions may be awarded for violation of these regulations.

7099 DEFINITIONS

7099.1 As used in this chapter, the following terms and phrases shall have the meaning ascribed:

Act – Section 316 of the Condominium Act of 1976, effective March 8, 1991 (D.C. Law 8-233; D.C. Official Code § 42-1903.16) (2001).

Agency –D.C. Department of Housing and Community Development, or any successor agency.

Claim – Any written notification to the Director by the Owner claiming that the Declarant is in violation of § 316 of the Act (D.C. Official Code § 42-1903.16) or any of provision of this chapter.

Common Elements – All portions of the Condominium other than the Units.

Condominium – Real estate, portions of which are designated for separate ownership and the remainder of which is designated for common ownership solely by the Owners of the portions designated for separate ownership.

Construction or Conversion Costs – All direct costs the Declarant incurred in connection with the construction or conversion, including the cost of labor and construction materials the Declarant incurred to construct or convert the structure. For purposes of this chapter, the construction or conversion costs shall not include any other costs incurred in connection with the construction or conversion such as architectural, engineering, legal or other consulting fees and charges, land acquisition costs, financing fees and charges, permit costs or fees, real estate and other commissions or charges, marketing and advertising costs, or similar ancillary costs or expenses.

Conversion Condominium – An existing building whose use is converted to a Condominium.

Convertible – A portion of land that may be converted to Condominium use in accordance with D.C. Official Code 42-1901.

Conveyance – The transfer of title by written deed instrument.

Declarant – Any person or group of persons acting in concert who:
(a) Offers to dispose of the person's or group's interest in a Condominium Unit not previously disposed of;
(b) Reserves or succeeds to any special Declarant right; or
(c) Applies for registration of the Condominium.

Director –The head of the Agency.

Letter of Registration – A written notice issued by the Agency registering the residential Condominium Units and certifying that the Declarant's Registration Package complies with the Act.

Lien – The value of Declarant's equity in a Unit or Units computed as ninety percent (90%) of the current listed sales price of the Unit or if not listed, the current list price of comparable Units in the Condominium secured by at a minimum, an assignment agreement collateralized by a recordable mortgage or recordable deed of trust reviewed and approved by the Director.

Owner – A Unit Owner in the case of a Structural Defect Claim for a Unit, or a Unit Owners association in the case of the Common Elements of the Condominium as applicable.

Purchaser – Any person, other than a Declarant or a person in the business of selling real estate for his or her own account, who by means of a voluntary transfer, acquires a legal or equitable

interest in a Condominium Unit other than a leasehold interest, including a renewal option, of less than 20 years, or a security for an obligation.

Mayor – The Mayor of the District of Columbia.

Registration Package – The application for Condominium registration including without limitation, an application, a certificate of eligibility to convert, an architect's report (if applicable), a public offering statement, a Condominium declaration, bylaws, preliminary plats and plans, a Unit purchase agreement, a sample deed of conveyance, limited warranty agreements, a letter of intent, and the condition of title.

Security or Security Interest – A form of security as approved by the Agency and being a liquid asset with immediately available funds which may be drawn upon to satisfy the Declarant's warranty obligations.

Structural Defect – A defect in a component that constitutes any Unit or portion of the Common Elements that reduces the stability or safety of the structure below standards commonly accepted in the real estate market, or restricts the normally intended use of all or part of the structure and which requires repair, renovation restoration or replacement.

Unit – A portion of the Condominium designed and intended for individual ownership.

APPENDIX OF FORMS

FORM 1: SAMPLE LETTER OF CREDIT

[FINANCIAL INSTITUTION LETTERHEAD]

Irrevocable Standby Letter of Credit No. _____

Date: _____

Expiry Date: Two Years after the Sale of the Final Residential Unit in the _____ Condominium

Beneficiaries:
The Mayor of the District of Columbia
or His Designee
c/o Rental Conversion and Sales Division
[contact the Agency for mailing address]
-and-
The _____
Condominium Unit Owners Association

Applicant:
[Applicant Name]
[Address]

Re: _____ Condominium
[Condominium Street Address]

We, _____ [Financial Institution Name] (the "Bank") with headquarters at _____ [Bank Telephone Number and Address for Letter of Credit Department] effective the _____ [Day, Month and Year], hereby authorize the above-named beneficiaries to draw on the Bank for the account of _____ [Applicant Name] up to an aggregate amount of USD _____ ($_____) [10% of Construction Costs], available by payment against your draft(s) at sight drawn on _____ [Bank Name] accompanied by the following documents:

1. This original letter of credit and any subsequent amendments;

2. The beneficiaries' affidavit that:

   (a) the Applicant failed to comply with the requirements of Section 316 of the Condominium Act of 1976, effective October 22, 1999, D.C. Law 13-46; D.C. Official Code § 42-1903.16 (2001) (the "Act");

   (b) the proceeds of the Beneficiaries' draft submitted herewith shall be solely used to fund the Applicant's warranty obligations under Section 316 (D.C. Official Code § 42-1903.16; and

(c) the Applicant received written notice of the Beneficiaries' intent to draw upon this letter of credit prior to the date of any draft.

3. A written statement signed by the Mayor of the District of Columbia or His Designee and a member of the _____ Condominium Unit Owners Association certifying that the amount of the draft drawn under _____ [Bank Name] Letter of Credit No. _____ represents funds due and payable from _____ [Applicant Name].

4. The amount of the draft drawn hereunder must be endorsed by the Beneficiaries on the reverse side thereof. All drafts must be marked "Drawn under Irrevocable Letter of Credit No. _____, dated _____ [Letter of Credit Date] for the _____ Condominium."

Presentation of drafts drawn hereunder may be made at any time on or before the expiry date hereof at our office located at _____ [Bank Name], _____ _____ [Street Address], Washington, D.C. _____ [Zip Code].

The amount of this letter of credit may be reduced from time-to-time by amendments in accordance with section 316(e)(1)) of the Act (D.C. Official Code § 42-1903.16(e)(1)), with such reduction being subject to the Mayor of the District of Columbia or His Designee's acceptance thereof.

This letter of credit expires at this office two years after the sale of the final residential condominium unit in the _____ Condominium. It is a condition of this letter of credit that it shall be deemed automatically extended for an additional one (1) year period from the current or future expiry date unless sixty (60) days prior to such expiry date, we notify you in writing by registered or certified mail, hand delivery, or courier service to each beneficiary that we elect not to extend this letter of credit for any such additional period. In the event you receive our notice of nonextension, you may draw under the letter of credit by your sight draft accompanied by your draft and signed statement: "The amount of our drawing represents funds due us as _____ [Bank Name] has elected not to extend their Letter of Credit No. _ _____ and we have not released _____ [Applicant Name] of their liability with us."

Multiple drawings are permitted. The _____ [Bank Name] shall have no right, duty, obligation or responsibility to evaluate the performance or nonperformance of the underlying contract between the Applicant and the Beneficiaries together or separately.

Any notice to the Beneficiaries in connection with this letter of credit shall be delivered in hand with receipt acknowledged or by certified mail, or courier service to the Beneficiaries' address set forth above.

This undertaking is issued subject to the International Standby Practices 1998, International Chamber of Commerce Publication No. 590.

We hereby agree with you that any draft(s) drawn under and in compliance with the terms of this letter of credit will be duly honored in immediately available funds upon presentation on or before the expiry date or any automatically extended expiry date and at the place named herein. If a demand for payment does not conform to the terms and conditions of this letter of credit, we will give prompt notice that the demand for payment was not effected in accordance with the terms and conditions of this letter of credit, we will state the reasons therefore and upon your instructions hold any documents at your disposal or return the same to you. Upon being notified that the demand for payment was not affected in conformity with the terms and conditions of this letter of credit, you may correct any such nonconforming demand for payment to the extent possible before the expiration date.

(Authorized Signature)
[Signatory Name]
[Bank Name]
[Telephone Number]

FORM 2: SAMPLE BOND

THE MAYOR OF THE DISTRICT OF COLUMBIA

Bond No. _____

KNOW ALL MEN BY THESE PRESENTS, that we _____ [Applicant's Name], hereinafter called the "Principal," and _____, [Bond Issuer's Name] a limited liability company/corporation/partnership organized and existing under the laws of the state of _____ and authorized to transaction business in the District of Columbia, hereinafter called the "Surety," are held unto the Mayor of the District of Columbia or His Designee, a body corporate and politic, as "Obligee," hereinafter called the "District of Columbia," in the sum of _____ ($_____ _____) lawful money of the United States of America, for the payment of which sum well and truly to be made, the.
Principal and the Surety bind themselves, their heirs, executors, administrators, successors and assigns, jointly and severally, firmly by their presents.

WHEREAS, the Principal completed construction of condominium units located at the __ _____ Condominium, _____ [Project Address], Washington, D.C., and

WHEREAS, the Principal registered the condominium with the appointed and designated District of Columbia agency, Registration No. _____, and

WHEREAS, the Principal must comply with Section 316 of the Condominium Act of 1976, effective October 22, 1999 (D.C. Law 13-46; D.C. Official Code § 42-1903.16) (2001), hereinafter the "Condominium Act," and to warranty obligations thereunder for the period beginning _____ and ending two years after the sale of the last residential unit in the _____ Condominium.

NOW THEREFORE, the condition of this obligation is such that if the Principal shall promptly and faithfully accomplish each and every, all and singular, the matters and things in the Condominium Act and its warranty obligations hereunder, or if the Surety shall pay over, make good and reimburse to the District of Columbia as set forth in the Condominium Act within thirty (30) days of demand by the District of Columbia after default, then this obligation shall be void, otherwise to be and remain in full force and effect.

PROVIDED HOWEVER, no right of action shall accrue on this bond to or for the use of any person, firm or corporation other than the District of Columbia named herein or its successors in office.

SIGNED AND SEALED this _____ day of _____, _____.

IN THE PRESENCE OF:

ATTEST: PRINCIPAL: _____

_____ By: _____

WITNESS: SURETY: _____

_____ By: _____

All persons desiring to comment on these proposed regulations should submit comments in writing to Paul Waters, Legislative Liaison, Department of Consumer and Regulatory Affairs, Suite 9400, 941 North Capitol Street, NE, Washington, D.C. 20002, not later than forty-five (45) days after publication of this notice in the *D.C. Register*. Copies of the proposed rules can be obtained from the address listed above. A copy fee of one dollar ($1.00) will be charged for each copy of the proposed rulemaking requested

DEPARTMENT OF HEALTH

NOTICE OF PROPOSED RULEMAKING

The Director of the Department of Health ("Department"), pursuant to the authority set forth in section 19(a)(3) of the District of Columbia Pharmacist and Pharmacy Regulation Act of 1980, effective September 16, 1980 (D.C. Law 3-98; D.C. Official Code § 47-2885.18(a)(3)); the District of Columbia Uniform Controlled Substances Act of 1981, effective August 5, 1981 (D. C. Law 4-29; D.C. Official Code § 48-901.01 *et seq.*); Mayor's Order 98-48, dated April 15, 1998, Section 4902 of the Fiscal Year 2002 Budget Support Act of 2001, effective October 3, 2001 (D.C. Law 14-28; D.C. Official Code § 7-731); Section 15 of the District of Columbia Drug Manufacture and Distribution Licensure Act of 1990, effective June 13, 1990 (D.C. Law 8-137; D.C. Official Code § 48-714(a)); and Mayor's Order 98-88, dated May 29, 1998, hereby gives notice of his intent to take final rulemaking action to adopt the following amendments to chapter 10 (Registration of Manufacturers, Distributors, and Dispensers) of Title 22 of the District of Columbia Municipal Regulations (DCMR), in not less than thirty (30) days from the date of publication of this notice in the D.C. Register.

The purpose of these amendments is to change the term of a District of Columbia Controlled Substance Registration to two (2) years.

Title 22 (Public Health and Medicine) Chapter 10 is amended as follows:

Chapter 10 CONTROLLED SUBSTANCE REGISTRATION FOR MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS

Sections 1000.1 and 1000.2 are amended to read as follows:

1000.1 The rules in this chapter contain the procedures governing the registration and regulation of manufacturers, distributors, and dispensers of controlled substances pursuant to Title III of the District of Columbia Uniform Controlled Substances Act of 1981 (D.C. Law 4-29, effective August 5, 1981, §§ 48-901.02 et seq.)(2001), hereinafter referred to as the "Act."

1000.2 To the extent consistent with the Act, regulations promulgated by the Federal Government pursuant to Title 21, Chapter II, of the Code of Federal Regulations (21 CFR Part 1300 to End), and in effect as of the effective date of this chapter, shall be used as a guide in administering the Act.

Section 1002.1 through 1002.3 are amended to read as follows:

1002.1 Every person who manufactures, distributes, dispenses, or conducts research with any controlled substance, or who proposes to engage in the manufacture, distribution, dispensing, or conducting of research with any controlled substance

within the District of Columbia shall obtain biennially and maintain current a registration issued by the Director in accordance with this chapter, unless exempted by federal law, or District of Columbia law or pursuant to §§ 1002.4 and 1002.5 of this chapter.

1002.2 Persons conducting manufacturing activities of controlled substances outside of the District of Columbia and doing business within the District of Columbia shall obtain biennially a registration in accordance with the rules of this subtitle, unless exempted by federal or District of Columbia law or pursuant to §§ 1002.4 and 1002.5 of this chapter.

1002.3 Out-of-state persons conducting distributing activities of controlled substances to persons within the District of Columbia shall obtain biennially a registration in accordance with the rules of this subtitle, unless exempted by federal or District of Columbia law or pursuant to §§ 1002.4 and 1002.5 of this chapter.

Section 1003 is amended to read as follows:

1003 REGISTRATION

1003.1 Unless otherwise exempted by federal law or this chapter, a person shall register with the Department and obtain and maintain a registration certificate before the person:

(a) Manufactures, distributes, or dispenses controlled substances in the District;

(b) Conducts research or instructional activities with controlled substances listed in Schedules II through V in the District;

(c) Conducts research or instructional activities with a controlled substance listed in Schedule I in the District;

(d) Conducts a chemical analysis with controlled substances listed in any schedule in the District; or

(e) Engages in any other activity for which registration is required.

1003.2 For practitioners, a District of Columbia controlled substances registration issued pursuant to this chapter shall expire simultaneously with the expiration of the practitioner's District of Columbia health professional license, certification, or occupation registration.

1003.3 For non-practitioners, a District of Columbia controlled substance registration issued pursuant to this chapter shall expire at 12:00 midnight of December 31 of each even-numbered year.

1003.4 Applications to renew a registration must be filed in a timely manner, not less than sixty (60) days prior to the expiration of the registration.

1003.5 A registration certificate expires on the date shown on the certificate.

1003.6 The Director shall mail a renewal application or a notice to renew to a registrant not less than thirty (30) days before the expiration date shown on the certificate.

1003.7 If a person fails to apply for renewal of a registration before the expiration date of his or her registration, he or she shall thereafter apply for a new registration and the prior registration shall be deemed to have expired on the date specified on the registration.

1003.8 Any person who is required to be registered and who is not so registered may apply for registration at any time and may obtain an application form by writing to the Department of Health's Pharmaceutical Control Division, 717 14th Street, NW., 6th Floor, Washington, D.C. 20005.

1003.9 To apply for a controlled substances registration, an applicant shall:

(a) Submit a completed application to the Department on the required forms which shall be signed by the:

(1) Applicant, if an individual;

(2) General partner, if the applicant is a partnership; or

(3) Officer responsible for the applicant, if the applicant is a corporation or other entity; and

(b) Pay all applicable fees.

1003.10 Applications submitted for filing shall be dated upon receipt. Applications which are complete shall be accepted for filing. Applications failing to comply with the requirements set forth in this chapter and the Act shall not be accepted for filing.

1003.11 In the case of minor defects as to completeness, the Director may accept the application for filing with a request to the applicant for additional information.

1003.12 A defective application shall be returned to the applicant within ten (10) days following its receipt with a statement of the reason for not accepting the application for filing.

1003.13 A defective application may be corrected and resubmitted for filing at any time; the Director shall accept for review any application upon resubmission by the applicant.

1003.14 Accepting an application for filing does not preclude any subsequent request for additional information pursuant to this chapter and has no bearing on whether the application will be granted.

1003.15 If the information requested on the application is not applicable to the applicant, the applicant shall indicate such on the form.

1003.16 The Director may require an applicant to submit additional documentation pertinent to the registration or written statements in support of an application to:

(a) Clarify application information; or

(b) Determine if the applicant meets the requirements of this chapter.

1003.17 The Director may deny an application if the applicant fails to provide information within fifteen (15) days of receipt of the Director's request.

1003.18 An application shall be considered withdrawn if the following occurs:

(a) The applicant requests its return; or

(b) The applicant fails to respond to a registered or certified letter regarding the application within fifteen (15) days of its delivery to the applicant.

Section 1004 is repealed.

Section 1015.1 is amended to read as follows:

1015.1 Unless the Act or this chapter otherwise provide, all notice required under this chapter to be sent to the Department or Director shall be sent to the Department of Health, Pharmaceutical Control Division, 717 14th Street, NW, 6th Floor, Washington, DC 20005, or to its successor agency by certified mail, return receipt requested.

Section 1030.1 is amended to read as follows:

1030.1 The fees for a controlled substances registration shall be as follows:

(a) Initial registration-- $130.00

(b) Biennial renewal -- $130.00

(c) Late filing-- $35.00

(d) Duplicate certificate-- $25.00

(e) Reinspection-- $130.00

Section 1099.1 is amended by repealing the following terms:

Act- District of Columbia Uniform Controlled Substances Act of 1981, D. C. Law 4-29, effective August 5, 1981.

Department- the Department of Consumer and Regulatory Affairs or its successor agency.

Director- the Director of the Department of Consumer and Regulatory Affairs of the Director's designee.

and substituted by the terms with the ascribed meanings as added:

Act- District of Columbia Uniform Controlled Substances Act of 1981, effective August 5, 1981, (D. C. Law 4-29; D.C. Official Code § 48-901)(2001).

Department- Department of Health

Director- Director of the Department

Federal Act- means the Controlled Substance Act (84 Stat. 1242; 21 U.S.C. 801) or the Controlled Substance Import and Export Act (84 Stat. 1285; 21 U.S.C. 951).

Practitioner—an individual licensed, registered, certified, or otherwise permitted by law to prescribe, dispense, and to administer drugs or medical devices, or to conduct research with respect thereto, within the course of such persons' professional practice or research.

All persons desiring to comment on the subject matter of this proposed rulemaking action shall submit written comments, not later than thirty (30) days after the date of publication of this notice in the D.C. Register, to the Department of Health, Office of the General Counsel, 825 North Capitol Street, N.E., 4th Floor, Washington, D.C. 20002. Copies of the proposed rules may be obtained between the hours of 9:00 a.m. and 5:00 p.m. at the address listed above.

DEPARTMENT OF HEALTH

NOTICE OF PROPOSED RULEMAKING

The Director of the Department of Health, pursuant to the authority set forth in D.C. Official Code § 47-2885.18 (a)(3)); the District of Columbia Uniform Controlled Substances Act of 1981, effective August 5, 1981, (D. C. Law 4-29; D.C. Official Code § 48-903.01); Mayor's Order 98-48, dated April 15, 1998, Section 4902 of the Fiscal Year 2002 Budget Support Act of 2001, effective October 3, 2001, (D.C. Law 14-28; D.C. Official Code § 7-731); Section 15 of the District of Columbia Drug Manufacture and Distribution Licensure Act of 1990, effective June 13, 1990, (D.C. Law 8-137; D.C. Official Code § 48-714(a)); and Mayor's Order 98-88, dated May 29, 1998; hereby gives notice of his intent to amend Title 22 of the District of Columbia Municipal Regulations Chapter 19 (Pharmacies).

The purpose of the amendments is to bring the regulations in line with the current practices and trends in the operation of pharmacies by adding provisions requiring registration of nonresident pharmacies that dispense or distribute prescription drugs or medical devices into the District, for the use of automated medication dispensing systems, the provision of remote automated pharmacy services, the provision of telepharmacy services, requiring pharmacists to perform prospective drug regimen reviews, requiring pharmacists to offer patient counseling services to all patients, and changing the term of a pharmacy license to two (2) years.

Proposed Rulemaking was published on May 11, 2007 at 54 DCR 4421. The Department received written comments from New Hampshire Pharmacy and Medical Equipment, the National Association of Chain Drugs Stores, Kaiser Permanente, The Washington DC Pharmacy Association, The Department of Mental Health, The Medical Assistance Administration, Sibley Memorial Hospital Department of Pharmacy, Mednovations, the D.C. Drug Utilization Review Board, and Care Pharmacies, Inc.

With the exception of the National Association of Chain Drugs Stores, Kaiser Permanente, and Mednovations, the public comments were limited to § 1925.3 regarding investigations and inspections of pharmacies. Additionally, the Department elected for administrative convenience to change the term of the pharmacy license to two (2) years. The Department has amended proposed rulemaking §§ 1900.5, 1902.17, 1903, 1911.9, 1912.2, 1912.4, 1913.4(g), 1913.5, 1913.6, 1914.2(b)(2), 1914.9, 1917.4, 1917.7(g), 1923.1, 1925, and 1999.1. Therefore these rules are being republished to provide thirty (30) days to receive comments on the revised rulemaking. These Proposed Rules supercede those published on May 11, 2007.

Final rulemaking action to adopt these amendments shall be taken in not less than thirty (30) days from the date of publication of this notice in the D.C. Register.

The following rulemaking action is proposed:

TITLE 22 District of Columbia Municipal Regulations, (PUBLIC HEALTH AND MEDICINE)(August 1986) Chapter 19 (Pharmacies) is amended as follows:

Sections 1900 to 1916 are amended to read as follows:

1900 GENERAL PROVISIONS

1900.1 It shall be unlawful for any person to operate, maintain, open, or establish a pharmacy within the District of Columbia without a valid license or registration from the Mayor.

1900.2 It shall be unlawful for an establishment or institution, or any part thereof, that does not provide services of the practice of pharmacy, as defined within, to use or have upon it, or displayed within it, or affixed to, or used in connection with it, a sign bearing the word or words "pharmacy," or "apothecary," "drug store," "druggist," or any word or words of similar or like import which would tend to indicate that the practice of pharmacy is being conducted in the establishment or institution.

1900.3 No drugs shall be permitted within a pharmacy until a license is obtained from the Director.

1900.4 A pharmacy shall maintain written policies and procedures regarding appropriate cleanliness and hygiene practices and ensure that its employees comply with the established policies and procedures.

1900.5 A pharmacy shall:

(a) Review its written policies and procedures, as necessary but at least biennially,

(b) Revise them as necessary, and

(c) Document the review.

1901 GENERAL OPERATING STANDARDS

1901.1 A pharmacy shall be operated only by pharmacist holding a valid license in the District of Columbia to practice pharmacy or, if a non-resident pharmacy, a valid license in the state in which the pharmacy is physically located.

1901.2 A licensed pharmacist shall be on duty at all times that a pharmacy is open for business. Where only one pharmacist is on duty, the pharmacy shall be closed for business during the pharmacist's meal period and breaks.

1901.3 The following items shall be posted conspicuously in the vicinity of the pharmacy practice area:

(a) Certificate of Occupancy Permit (where applicable);

(b) Pharmacy license;

(c) Federal and District of Columbia Controlled Substances Registrations;

(d) Professional licenses of pharmacists on duty;

(e) Certificates of registration of pharmacy interns; and

(f) The hours that the pharmacy is open for business.

1901.4 A pharmacy shall stock, maintain, sell, compound, dispense, and distribute only FDA registered drugs, medical devices, and chemicals for compounding.

1901.5 A pharmacy shall sell, dispense, or otherwise distribute only drugs and medical devices that are safe for their intended purposes, and that are neither misbranded nor adulterated.

1901.6 Drugs and medical devices with expired dating, or that are otherwise misbranded or adulterated, shall not be stored with currently dated products or those that are safe for their intended purposes, but shall be separated from active stock and so identified.

1901.7 A pharmacy shall only obtain a drug or medical device from a pharmacy, manufacturer, distributor, or wholesaler that is registered or exempted from registration in the District of Columbia pursuant to § 302 (c) of the Uniform Controlled Substances Act or, if a non-resident pharmacy, be registered or exempted from registration by the federal government or the state in which the pharmacy, manufacturer, distributor, or wholesaler is located.

1901.8 Burglaries and damage to a pharmacy or its inventory by fire, flood, or other causes shall be reported immediately by the licensee or agent of the licensee to the Director.

1901.9 Neither drugs nor other merchandise shall be dispensed, sold, held for sale, or given away in any pharmacy damaged by fire, flood, or other causes until the Director or designee has determined that the merchandise is not adulterated or otherwise unfit for sale, use, or consumption. Damaged premises shall be inspected by the Director or designee to determine their continued suitability for pharmacy operations.

1901.10 Chapter 65 (Pharmacists) of Title 17 DCMR and Chapter 13 of Title 22 DCMR supplement this chapter.

1902 NEW LICENSURE OF PHARMACIES

1902.1 Licenses shall be issued for the following categories of pharmacies as defined in this chapter, except for non-resident pharmacies, which shall be required to register with the Department:

(a) Retail pharmacy/community pharmacy;

(b) Nuclear pharmacy;

(c) Institutional pharmacy;

(d) Special or limited use pharmacy; and

(e) Non-resident pharmacy.

1902.2 A retail chain pharmacy with locations both in and outside of the District of Columbia shall obtain:

(a) A license for each location within the District of Columbia; and

(b) A registration pursuant to § 1903 for each location outside the District of Columbia which dispenses, distributes, ships, mails, or delivers, in any manner, prescription drugs or prescription medical devices directly or indirectly to a patient in the District of Columbia.

1902.3 The Director shall not license or register a pharmacy, person, or entity, which serves as a storefront, broker, agent, dealer, or in any way exists to facilitate the dispensing, shipping, mailing, delivery, or distribution of prescription drugs or devices from Canada, or any other jurisdiction outside of the United States, to District of Columbia residents.

1902.4 Except as otherwise provided in this chapter, an applicant for a new license to operate a pharmacy shall furnish proof satisfactory to the Director of the following:

(a) That a valid certificate of occupancy, where required by the Department of Consumer and Regulatory Affairs, has been issued for the premises where the pharmacy will be located;

(b) If the pharmacy is owned by a corporation, that the corporation is in good standing with the District of Columbia, or the state of incorporation if the pharmacy is incorporated in a state other than the District of Columbia;

(c) That each person listed on the application (individuals, partners, or officers of the corporation) has not been convicted of a felony involving drugs; and

(d) Other information as may be necessary to properly evaluate the applicant and the application.

1902.5 It shall be unlawful for any person to furnish false or fraudulent information on an application for a license or registration.

1902.6 The application for a pharmacy license shall be made on a form to be prescribed by the Director and shall include the required fee. No license fee shall be required for the operation of a pharmacy by the United States government or by the District of Columbia government.

1902.7 The application for a pharmacy license shall include the name and license number of the licensed pharmacist who shall be responsible for ensuring that the pharmacy complies with all applicable laws and regulations pertaining to the operation of the respective pharmacy and practice of pharmacy. The pharmacist shall be known as:

(a) The "pharmacist-in-charge" for a retail/community pharmacy, special or limited use pharmacy, or non-resident pharmacy;

(b) The "Director of Pharmacy" for an institutional pharmacy; and

(c) The "Responsible Nuclear Pharmacist" for a nuclear pharmacy.

1902.8 The proprietor of a pharmacy, or other appropriate individual, shall notify the Director within thirty (30) days after a change in the pharmacist-in-charge, Director of Pharmacy, or Responsible Nuclear Pharmacist.

1902.9 Prior to issuing a license, the Director shall make an inspection of a pharmacy to determine compliance with the Act and this chapter.

1902.10 The Director shall send a written report of the findings of the inspection to the licensee no later than fifteen (15) days after the conclusion of the inspection.

1902.11 The Director shall issue a license to a pharmacy that the Director determines is in compliance with the Act and this chapter.

1902.12 The Director shall indicate on the face of the license:

(a) The pharmacy classification for which the license is issued; and

(b) Any restrictions on the license for special or limited use pharmacies.

1902.13 A license is valid only for the proprietor, the premises, and the pharmacy name designated on the license and the location for which it is issued.

1902.14 A pharmacy license is not transferable.

1902.15 The pharmacy license shall be issued in the name of the proprietor whether or not the proprietor of a pharmacy is a pharmacist.

1902.16 A license is the property of the District of Columbia government and shall be returned to the Director immediately upon the occurrence of any of the following events:

(a) Suspension or revocation of the license;

(b) Refusal or failure to renew the license;

(c) Voluntary surrender by the licensee;

(d) Change in proprietorship of the pharmacy;

(e) Death of the proprietor;

(f) Failure of the pharmacy to open for business within thirty (30) days after the license has been issued, except that the Director may grant an extension at his or her discretion for good cause shown;

(g) Failure of the pharmacy to operate for any reason for more than ninety (90) consecutive days after it has opened for business; or

(h) Closure of the pharmacy.

1902.17 The term of a license issued or renewed pursuant to this chapter is two (2) years and shall expire on May 31 of each odd numbered year regardless of the issuance date unless the Director changes the renewal system pursuant to § 1902.18.

1902.18 The Director may change the renewal system to another system for the administrative convenience of the Director.

1902.19 If the Director changes the renewal system pursuant to § 1902.18 of this chapter, the term of a license that is in effect on the date of the Director's determination may be extended up to two (2) years in order to permit an orderly transition.

1903 REGISTRATION OF NONRESIDENT PHARMACIES

1903.1 The purpose of these rules is to provide standards for the operation of nonresident pharmacies, which dispense or distribute prescription drugs or medical devices, directly or indirectly such as through the use of an agent or intermediary, to persons located within the District of Columbia. The Department has determined

that these rules are necessary to protect the health and welfare of the citizens of the District of Columbia.

1903.2 Nonresident pharmacies which dispense, distribute, ship, mail, or deliver in any manner, prescription drugs or medical devices into the District of Columbia, directly or indirectly, shall, in addition to complying with all applicable federal laws, be registered by the Department and comply with the pharmacy and drug laws and regulations of the District of Columbia, unless and unto the extent that compliance would violate the pharmacy or drug laws or regulations in the state in which the nonresident pharmacy is located.

1903.3 No person or entity required to be registered shall ship, mail, or deliver in any manner, prescription drugs or medical devices into the District of Columbia, directly or indirectly, until a Certificate of Registration is issued by the Department.

1903.4 A nonresident pharmacy shall:

(a) Register with the Department on a form provided by the Department and pay the required fee (no registration fee shall be required for the registration of a nonresident pharmacy operated by the United States government or any other state government); and

(b) Biennially renew the registration and pay the required fee.

1903.5 The term of a registration issued or renewed pursuant to this chapter is two (2) years, or the balance of the registration period, whichever is shorter, and shall expire on May 31 of each odd numbered year regardless of the issuance date unless the Director changes the renewal system pursuant to § 1903.6.

1903.6 The Director may change the renewal system to another system for the administrative convenience of the Director.

1903.7 If the Director changes the renewal system pursuant to § 1903.6 of this chapter, the term of a registration that is in effect on the date of the Director's determination may be extended up to two (2) years in order to permit an orderly transition.

1903.8 As part of the application for registration or renewal of registration, a nonresident pharmacy shall:

(a) Submit evidence to the Department that the nonresident pharmacy holds a pharmacy license, registration, or permit, in good standing, issued by the state in which the pharmacy is located;

(b) Submit evidence to the Department that the nonresident pharmacy holds a

valid DEA registration number, if the pharmacy dispenses prescription controlled substances listed in any Schedule into the District of Columbia;

(c) Submit evidence that the pharmacist in charge holds a valid license in good standing in the state in which the nonresident pharmacy is located;

(d) Provide the name, address, and title of its:

(1) Owner or proprietor;

(2) Pharmacist-in-charge, along with his or her license number and state of licensure;

(3) Principal corporate officers;

(4) Pharmacists who are dispensing prescription drugs or medical devices to citizens of the District of Columbia, along with their license numbers and state of licensure; and

(5) Resident agent located within the District of Columbia designated to accept service of process;

(e) Submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agent of the state in which the nonresident pharmacy is located;

(f) Submit an affidavit by the pharmacist-in-charge certifying that the pharmacist-in-charge has read and understands the pharmacy and drug laws and regulations of the District of Columbia, and that the pharmacist-in-charge has made the pharmacy and drug laws and regulations of the District of Columbia available to all pharmacists working in the nonresident pharmacy;

(g) Provide evidence of the nonresident pharmacy's ability to provide to the Department a record of a prescription order dispensed to a resident of the District of Columbia not later than three (3) business days after the time the Department requests the record; and

(h) Provide all website address(es) and domain registration(s) to the Department, if applicable;

(i) If the nonresident pharmacy is solely internet-based or operates primarily as an internet-based pharmacy, the pharmacy shall also:

(1) Submit proof acceptable to the Department of certification by the Verified Internet Pharmacy Practice Sites Program (VIPPS) of the National Association of Boards of Pharmacy, or other national certification

program for internet pharmacies acceptable to the Department, for each website and domain registration; and

(2) Submit proof of registration in good standing in the District of Columbia as a foreign corporation.

1903.9 The Director shall deny an application for registration if the applicant fails to provide the required information or documentation.

1903.10 A nonresident pharmacy shall report a change in the name or address of the resident agent in writing to the Department within thirty (30) days after the change.

1903.11 A nonresident pharmacy shall report a change in the pharmacist-in-charge, or corporate officers within thirty (30) days after the change.

1903.12 A nonresident pharmacy which changes proprietorship or ownership, its name, or location shall notify the Department within ten (10) days after the change and apply for a new registration.

1903.13 A nonresident pharmacy shall notify the Department within ten (10) days after closing.

1903.14 A nonresident pharmacy shall, during its regular hours of operation, but not less than six (6) days per week, and a minimum of forty (40) hours per week, provide toll-free telephone communication consultation between patients in the District of Columbia and a licensed pharmacist at the pharmacy who has access to the patient's prescription records. This toll-free number shall be disclosed on a label affixed to each container of drugs or medical device dispensed to patients in the District of Columbia.

1903.15 A nonresident pharmacy shall immediately communicate to a patient or prescribing practitioner any expected delay in delivering the prescribed drug or device which might jeopardize or alter the drug therapy of the patient.

1903.16 A nonresident pharmacy shall maintain, at all times:

(a) A license, registration, or permit in good standing issued in the state in which it is located;

(b) Its records of prescription drugs and devices dispensed to patients in the District of Columbia so that the records are readily retrievable, in hardcopy or electronically, for a period of five (5) years from the date of first dispensing. Records which are more than two (2) years old may be stored offsite as long as they can be retrieved within three (3) business days of a request;

(c) Compliance with the laws and regulations regarding confidentiality of prescription records in the state in which it is located, and if there are no such laws in that state, then the pharmacy shall comply with the confidentiality laws and regulations of the District of Columbia;

(d) Compliance with all requests for information made by the Department pursuant to this section; and

(e) If the pharmacy is internet-based or primarily internet-based:

(1) Certification by the Verified Internet Pharmacy Practice Sites Program (VIPPS) of the National Association of Boards of Pharmacy, or other national certification program for internet pharmacies acceptable to the Department, for each website and domain registration; and

(2) Registration in good standing in the District of Columbia as a foreign corporation.

1903.17 By applying for and being granted registration as a nonresident pharmacy in the District of Columbia, a nonresident pharmacy shall be deemed to have given its consent to provide to the Department, not later than three (3) business days after the time the Department requests the record:

(a) All Information and records concerning a prescription drug or medical device order dispensed to a resident of the District of Columbia;

(b) Any inspection reports, warning notices, notice of deficiency reports, disciplinary actions or any other related reports from the state in which it is located concerning the operation of the nonresident pharmacy for review of compliance with state and federal drug laws; and

(c) All information requested by the Department.

1903.18 If a nonresident pharmacy fails to comply with any provision of § 1903.17 the Department may summarily suspend the registration. The Department may lift a summary suspension imposed under this section if the Department determines that the nonresident pharmacy has provided the requested information or records.

1903.19 In addition to any other appropriate remedies or actions, the Director shall withdraw the registration of a registrant that:

(a) Loses licensure in good standing in the state in which it is located;

(b) Loses registration in good standing in the District of Columbia as a foreign corporation; or

(c) Is conducted in a manner that endangers the public health, welfare and safety.

1903.20 When withdrawing a registration pursuant to § 1903.19 of this chapter, the Director shall give written notice to the registrant citing the basis for withdrawal. The effective date of withdrawal shall be thirty (30) calendar days from the date of service of the notice, or immediately, in the case of danger to the public health, safety, or welfare.

1903.21 The notice required in § 1903.20 of this chapter shall state that the registration shall be automatically withdrawn unless, prior to the effective date, the registrant submits proof satisfactory to the Director that the registrant has the licensure or registration required pursuant to § 1903.16.

1903.22 In the case of a withdrawal that is effective immediately, the registrant may seek reinstatement of the registration by submitting proof satisfactory to the Director that the registrant no longer poses a danger to the public health, safety, or welfare.

1903.23 In addition to any other appropriate remedies or actions, the Director may fine, suspend, or withdraw the registration of a registrant that violates the pharmacy or drug laws or regulations of the state in which it is located, the District of Columbia, or the United States; or causes harm or injury to a person in the District of Columbia.

1903.24 A registrant shall be afforded notice and, upon written request received by the Director within thirty (30) days of the receipt of the notice, an opportunity to be heard prior to the Director taking action pursuant to § 1903.19 against the registrant.

1903.25 Once a registration has been withdrawn, a registrant shall not ship, mail, or deliver in any manner, prescription drugs or medical devices into the District of Columbia, whether directly or indirectly.

1903.26 Upon receipt of a complaint against the nonresident pharmacy, the Department shall forward the complaint to the state where the nonresident pharmacy is located.

1903.27 The Department will extend reciprocal cooperation to any state that licenses or registers nonresident pharmacies for the purpose of investigating complaints against pharmacies located in the District of Columbia or the sharing of information and investigative reports, as long as the other state will extend the same reciprocal cooperation to the Department.

1904 RENEWAL OF PHARMACY LICENSE

1904.1 The Director shall mail a renewal notice to a licensee by first class mail to the licensee's last known address on file with the Director at least sixty (60) days prior to the expiration of the license.

1904.2 The failure of a licensee to receive the renewal notice required by this section does not relieve the licensee of the responsibility of renewing the license by the expiration of the existing license.

1904.3 A licensee applying for renewal of a license shall submit the application for renewal not less than thirty (30) days prior to its expiration, to avoid lapse.

1904.4 If the Director does not receive the application for renewal of a license at least thirty (30) days prior to the expiration date, the license shall lapse on the expiration date. The licensee may be reinstated within thirty (30) days of expiration upon receipt of a completed renewal application and the payment of a late fee.

1904.5 Upon receipt of the required late fee and final processing of the renewal application, the licensee shall be deemed to have possessed a valid license during the period between the expiration of the license and the reinstatement date.

1904.6 Reinstatement of a license that has been expired for over thirty (30) days shall be at the discretion of the Director. Otherwise, a licensee that fails to submit the completed renewal application or required late fee within thirty (30) days after the expiration of the applicant's license shall be required to apply for new licensure pursuant to § 1902 of this chapter.

1904.7 Prior to the renewal of a license, the Director shall make an inspection of a pharmacy to determine compliance with the Act and this chapter.

1904.8 The Director shall send a written report of the findings of the inspection to the licensee no later that fifteen (15) days after the conclusion of the inspection.

1905 CHANGE IN PHARMACY NAME, PROPRIETORSHIP, OR LOCATION

1905.1 A proprietor desiring to change the name of a pharmacy shall apply to the Director on a form prescribed by the Director and pay the required fee.

1905.2 A proprietor desiring to change the location of a pharmacy within the District shall apply for a new license in accordance with the requirements set forth in § 1902 of this Chapter.

1905.3 If the change of name or location is approved, the Director shall issue a new license indicating the new name or location. The licensee is not permitted to use the new name or location until it has received official notification from the

Director of approval of the change.

1905.4 A proprietor desiring to change the proprietorship of a pharmacy shall notify the Director at least sixty (60) days prior to the date of the change. The prospective proprietor shall apply for a new license in accordance with § 1902 of this chapter.

1905.5 When a pharmacy changes proprietorship, the license shall become void and shall be surrendered promptly to the Director, and a license shall be obtained by the new proprietor whether or not there is any change in the name of the pharmacy.

1905.6 The Director may issue a license to a new proprietor of a pre-existing licensed pharmacy without a pre-licensure inspection as required by § 1902.9 of this chapter, provided the new proprietor certifies in the application for a new license that the pharmacy will not undergo substantial physical or operational changes in the first year of licensure.

1906 CLOSING A PHARMACY

1906.1 Whenever a pharmacy plans to discontinue operation, the proprietor shall, in addition to the requirements of this section, comply with the provisions of § 1323 of this Title, and notify the Director of the closing of the pharmacy not later than fifteen (15) days prior to the anticipated date of closing. The notice shall be submitted to the Director in writing and shall contain the following information:

(a) The date the pharmacy will close;

(b) The names, addresses, and telephone numbers of the persons who shall have custody of the prescription files, the bulk compounding records, the repackaging records, all drugs including the controlled substances, and inventory records of the pharmacy to be closed; and

(c) The names, addresses, DEA registration numbers, and District registration numbers of any persons who will acquire any of the drugs and controlled substances from the pharmacy to be closed, if known at the time the notification is filed.

1906.2 A pharmacy that dispenses prescription drugs shall, at least fifteen (15) days prior to the closing date of the pharmacy, post a closing notice sign in a conspicuous place in the front of the prescription department and at all public entrance doors to the pharmacy. The closing notice sign shall contain the following information:

(a) The date of closing; and

(b) The name, address, and telephone number of the pharmacy acquiring the prescription drug orders, refill information, and patient medication records of the pharmacy.

1906.3 On the date of closing, the pharmacy shall, in addition to complying with all other District and federal requirements:

(a) Transfer the prescription drug files, refill information, and patient medication records to a licensed pharmacy within a reasonable distance of the closing pharmacy. The pharmacy shall be the same pharmacy which was identified in the closing notice sign; and

(b) Remove all signs and symbols indicating the presence of a pharmacy, or any representation that would tend to mislead the public that pharmacy is located at the address.

1906.4 Not later than fifteen (15) days after the pharmacy has closed, the proprietor shall submit to the Director the following:

(a) The pharmacy license;

(b) The District of Columbia certificate of registration; and

(c) A written statement containing the following information:

(1) The actual date of closing;

(2) Confirmation that all drugs have been transferred to an authorized person or persons, or destroyed. If the drugs were transferred, the names and addresses of the persons to whom they were transferred;

(3) If controlled substances were transferred, a list of the names, addresses, DEA registration numbers, and District registration numbers of the persons to whom the substances were transferred, the substances transferred, the amount of each substance transferred, the date on which the transfer took place, and a copy of DEA form 222 for the transfer of Schedule II controlled substances;

(4) Confirmation that the DEA registration and all unused DEA 222 forms (order forms) were returned to the DEA;

(5) Confirmation that all pharmacy labels with addresses and blank prescription pads with addresses which were in the possession of the pharmacy were destroyed;

(6) If controlled substances were transferred, confirmation that an inventory

has been conducted; and

(7) Confirmation that all signs and symbols indicating the presence of the pharmacy have been removed.

1906.5 If a pharmacy is closed suddenly due to fire, destruction, natural disaster, death, property seizure, eviction, bankruptcy, or other emergency circumstances the pharmacy shall notify the Director immediately or as far in advance of the closing as allowed by the circumstances.

1906.6 The pharmacist-in-charge and the proprietor of the pharmacy shall be jointly responsible for ensuring the pharmacy's compliance with the provisions of this section.

1907 PHYSICAL STANDARDS

1907.1 The physical standards contained in this section shall apply to all pharmacies, unless otherwise exempted by this chapter or the Director.

1907.2 A pharmacy shall meet the applicable requirements of the District of Columbia zoning, building, fire, plumbing, and electrical codes.

1907.3 A pharmacy shall not be permitted to operate in either a temporary or trailer-type facility, except by special or limited use license as approved by the Director.

1907.4 The prescription drug compounding and dispensing area shall:

(a) Be a minimum of one hundred fifty (150) square feet in area, except that a pharmacy licensed prior to the effective date of these rules may be of a lesser square footage as approved by the Director;

(b) Have a minimum of ten (10) square feet of counter space for the pharmacist-in-charge, with additional space for each additional pharmacist on duty, to compound and dispense drugs safely and efficiently, except that a pharmacy licensed prior to the effective date of this chapter may be of lesser square footage of counter space as approved by the Director;

(c) Shall contain an area which is suitable for confidential patient counseling, if the pharmacy serves the public;

(d) Be separated from other areas by a barrier which renders the area inaccessible to unauthorized persons;

(e) Provide an unobstructed view of the pharmacist on duty;

(f) Be properly lighted and ventilated;

(g) Have a sink and goose-neck faucet with hot and cold running water within the dispensing and compounding area, for the immediate access and use of all pharmacy personnel, maintained in a sanitary condition and shall include:

(1) Soap or detergent; and

(2) Air-driers or single-use towels.

(h) Maintain the temperature of the pharmacy within a range compatible with the proper storage of drugs; and

(i) Have refrigeration facilities exclusively for the storage of drugs requiring cold storage with a thermometer controlling the interior temperature to keep it maintained between thirty-six degrees Fahrenheit (36°F) and forty-six degrees Fahrenheit (46°F).

1907.5 All areas where drugs and medical devices are stored, shall be dry, well lighted, well ventilated, maintained at a temperature safe for the storage of drugs as specified by the United States Pharmacopoeia/National Formulary (USP/NF) or the United States Food and Drug Administration (USFDA) and maintained in a clean and orderly condition.

1907.6 Storage areas shall be maintained at temperatures which will ensure the integrity of the drugs prior to their dispensing as stipulated by the United States Pharmacopoeia /National Formulary (USP/NF) and/or the manufacturer's or distributor's labeling unless otherwise indicated by the Bureau of Food, Drug & Radiation Protection, Pharmaceutical Control Division.

1908 SANITATION STANDARDS

1908.1 The sanitary standards contained in this section shall apply to all pharmacies and drug and medical device storage areas, unless otherwise exempted by this chapter or the Director.

1908.2 A pharmacy and all areas under the control of the pharmacy, including storage areas and restrooms, shall be maintained in a clean and sanitary condition free of infestation by rodents, birds, insects, and other vermin.

1908.3 All pharmacy and storage areas shall be dry and well ventilated.

1908.4 All pharmacy equipment shall be kept clean and in good operating condition.

1908.5 Trash shall be kept in opaque trash bags and covered waste receptacles.

1908.6 Trash, sewage, and other refuse shall be removed from a pharmacy in a timely

and sanitary manner.

1908.7 Restroom facilities shall be located in an area reasonably accessible to pharmacy personnel and supplied with a hand washing sink, soap or detergent, toilet paper, and air driers or single-service towels.

1908.8 The pharmacy's plumbing facilities shall be kept in good repair.

1908.9 Animals shall not be permitted in the pharmacy or areas immediately adjacent to and under the control of the pharmacy except for guide dogs accompanying disabled persons.

1908.10 All persons working in a pharmacy in any capacity shall follow hygienic work practices, including the washing of hands thoroughly as often as is necessary to remove soil and contamination.

1909 REQUIRED EQUIPMENT AND REFERENCES

1909.1 The equipment and references requirements of this section shall apply to all pharmacies, unless otherwise exempted by this chapter or the Director.

1909.2 The pharmacist-in-charge shall be responsible for maintaining the following:

(a) Current dispensing information reference source consistent with the scope of pharmacy practice at the location of the permitted pharmacy;

(b) A set of prescription balances, sensitive to 15 milligrams, and weights or an electronic scale if the pharmacy engages in dispensing activities that require the weighing of components;

(c) Other equipment, supplies, and references consistent with the pharmacy's scope of practice and with the public safety; and

(d) All other items required by federal and District of Columbia laws and regulations.

1909.3 A pharmacy may apply to the Director for a waiver of any of the equipment required under § 1909.2 where the equipment would be inapplicable to the services provided by the pharmacy.

1909.4 A pharmacy shall be equipped to provide emergency information about reactions to poisons from a current source.

1909.5 In addition to the requirements set forth under § 1909.2, a nuclear pharmacy shall maintain the following items, in hard copy or electronic format, in its reference library:

(a) A reference on the safe handling of radioactive materials;

(b) A minimum of three texts dealing with nuclear medicine science;

(c) A reference on sterile product preparation; and

(d) Code of Federal Regulations, Title 49, Parts 106-199, with recent amendments.

1910 SECURITY AND SAFEGUARDS AGAINST DRUG DIVERSION

1910.1 The security and safeguards requirements of this section shall apply to all pharmacies, unless otherwise exempted by this chapter or the Director.

1910.2 A pharmacy shall have a security alarm system which:

(a) Detects unauthorized entry into the premises;

(b) Provides zone protection for the drug storage, compounding, and dispensing areas;

(c) Has an auxiliary source of power; and

(d) Is in good repair and operating order at all times.

1910.3 The prescription drug compounding and dispensing area and the drug storage area shall be separately enclosed and secured in such a manner as to prevent diversion and authorized access.

1910.4 Any controlled substance stored outside of the prescription drug compounding and dispensing area shall be kept in a locked storage area.

1910.5 If only a designated area of an establishment is used as a pharmacy, the pharmacy area shall be securely enclosed and capable of being locked and equipped with an alarm system and inaccessible from the rest of the establishment.

1910.6 Each pharmacist, while on duty, shall be responsible for the security of the pharmacy, including provisions for effective control against theft or diversion of drugs or devices.

1910.7 A pharmacy shall be secured by either a physical barrier with a suitable lock, or by an electronic barrier to detect entry, and protected by an alarm at all times while a pharmacist is not on duty.

1910.8 Access to the prescription drug compounding, dispensing, and storage areas shall be restricted to:

(a) Pharmacists employed by the pharmacy;

(b) Ancillary persons who require entry for the purpose of discharging a job related duty in the presence of a pharmacist; and

(c) Persons legally entitled to engage in inspections or enforcement duties.

1910.9 The following drugs, medical devices, and medical supplies shall not be kept or displayed in an area that is accessible to the public:

(a) Prescription or legend drugs and medical devices;

(b) Devices that may be used in the administration of controlled substances;

(c) Over-the-counter medicine that contains a controlled substance; and

(d) Over-the-counter medicines that have been identified by the Food and Drug Administration or the Director as having a potential for misuse or abuse.

1911 PACKAGING AND HANDLING OF DRUGS AND MEDICAL DEVICES

1911.1 The packaging and handling requirements of this section shall apply to all pharmacies, unless otherwise exempted by this chapter or the Director.

1911.2 A pharmacy shall dispense drugs or medical devices in new and clean containers or in the manufacturer's original container or package.

1911.3 A pharmacy shall dispense drugs in child-resistant containers unless there is written documentation that the patient has requested otherwise, pursuant to the Federal Poison Prevention Act of 1970, 16 CFR Part 1700.

1911.4 A pharmacy shall not reuse a manufacturer's bottle or container.

1911.5 A pharmacy shall not reuse a bottle or container that has held toxic, adulterated, or misbranded substances.

1911.6 A pharmacy shall obtain drugs only from suppliers licensed or registered as required by federal and District law.

1911.7 A pharmacy shall obtain only drugs that are in the original manufacturer's or distributor's container.

1911.8 A pharmacist shall direct and supervise the compounding, repackaging, or prepackaging of drugs and make the final verification of the prepackaged product and document the verification.

1911.9 A pharmacy shall keep a log of drugs that have been compounded, repackaged, or prepackaged under a pharmacist's supervision. The log must contain the following information:

(a) The name of the drug;

(b) The name of the manufacturer or distributor;

(c) The manufacturer or distributor's lot or control number of the drug;

(d) The strength of the drug;

(e) The expiration date;

(f) The date of prepackaging or repackaging;

(g) The quantity of drugs prepared; and

(h) The name or initials of the pharmacist supervising the packaging.

1911.10 A pharmacy shall keep the log required under § 1911.09 of this chapter for five (5) years from the date of packaging. Records that are more than two (2) years old may be stored offsite as long as they can be retrieved within three (3) business days of a request.

1911.11 All drugs and medical devices held by a pharmacy shall be stored:

(a) In a proper and safe manner;

(b) In an appropriate container or package that provides for protection of the product;

(c) To insure complete and accurate identification of the product; and

(d) As required by the manufacturer, this chapter, and other applicable federal and District of Columbia laws or regulations.

1912 LABELING OF DISPENSED DRUGS

1912.1 The labeling requirements of this section shall apply to all pharmacies, unless otherwise exempted by this chapter or the Director.

1912.2 A container in which a prescription drug or device is sold or dispensed must bear a label containing the following information:

(a) The name, address, and telephone number of the pharmacy;

(b) The name of the patient, or if the ultimate user is an animal, the name of the owner, the first name of the animal, and the species of the animal;

(c) The name of the prescribing practitioner;

(d) The date of filling;

(e) The generic, chemical, or brand name of the drug unless omission is specifically requested by the prescriber in writing pursuant to the District of Columbia Prescription Drug Price Information Act, (D.C. Law 1-81, D.C. Code §§ 48-801 et al);

(f) The strength, dosage, and quantity of the drug dispensed;

(g) The directions for use and cautionary statements, if any, contained in the prescription or required by law;

(h) The serial number of the prescription or prescription number; and

(i) The expiration date of the product according to the manufacturer or one (1) year from the date the drug or medical device is dispensed, whichever comes first, subject to the discretion of the pharmacist to select an earlier date on which the life of a compounded drug product may expire.

1912.3 If a prescription order is for a controlled substance, the label shall also include a clear, concise warning that it is a crime to transfer the drug to any person other than the patient.

1912.4 A pharmacy shall be responsible for labeling each prepackaged or repackaged container with the following information:

(a) The name of the drug;

(b) The name of the manufacturer if the drug is generic;

(c) The drug strength and quantity;

(d) The manufacturer or distributor's control or lot number; and

(e) The expiration date of the product according to the manufacturer or on one (1) year from the date the drug or medical device is prepackaged, whichever comes first, subject to the discretion of the pharmacist to select an earlier date on which the life of a compounded drug product may expire.

1912.5 When the size of the label required pursuant to this section requires a reduction in type, the reduction shall not be made to a size smaller than is necessary and under no circumstances shall the size be less than six (6) point type.

1912.6 Once opened, a multi-dose container shall be labeled with the expiration date of the product according to the manufacturer or on one (1) year from the date the drug or medical device is prepackaged, whichever comes first, subject to the discretion of the pharmacist to select an earlier date on which the life of a compounded drug product may expire.

1913 RECORDKEEPING

1913.1 The recordkeeping requirements of this section shall apply to all pharmacies, unless otherwise exempted by this chapter or the Director.

1913.2 A pharmacy shall maintain on a current basis a complete and accurate record of all prescription drugs and devices received, sold, compounded, dispensed, or otherwise disposed of by the pharmacy for a period of five (5) years.

1913.3 For purposes of this section, the requirement may be met by maintaining the most recent two years of records on site and the remaining three years of records off site as long as the records can be retrieved within three (3) business days of a request.

1913.4 A pharmacy shall keep a chronological record, for a period of five (5) years from the date of first dispensing, of each prescription that is filled or refilled including the following information:

(a) The name and address of the patient;

(b) The name and address of the prescriber and date prescribed;

(c) The name, strength, dosage form, and quantity of the drug prescribed, and quantity dispensed if different from the quantity prescribed;

(d) The name and manufacturer of the drug if it is a substitute or generic drug for the drug actually prescribed or filled initially;

(e) Directions for use;

(f) The date the prescription was compounded, dispensed, or refilled;

(g) The name or initials of the pharmacist responsible for final verification of the prescription order;

(h) The prescriber's Drug Enforcement Administration (DEA) number and District of Columbia Controlled Substances number when required by law or regulation;

(i) The expiration date of the drug dispensed;

(j) Any change or alteration made to the prescription dispensed based on contact with the practitioner to show a clear audit trail. This shall include, a change in quantity, directions, number of refills, or authorization to substitute a drug; and

(k) Any other information required by District of Columbia or federal law or regulations.

1913.5 The pharmacist performing the final verification of a prescription shall be identified on the prescription record by name or initial, and shall be fully responsible for the accuracy of the processing, compounding, and dispensing of the prescription order.

1913.6 A pharmacy shall put in place systems to assign a secure identification code to each pharmacist for use on verification records, or require manual signatures of pharmacists performing final verifications to ensure that only the actual verifying pharmacist can place his or her name or initials on the verification records.

1913.7 All prescriptions orders shall be maintained for a period of five (5) years from the date of first dispensing.

1913.8 Prescription orders for controlled substances in Schedules I and II shall be maintained in a file separate from all other records of the pharmacy.

1913.9 Prescription orders for controlled substance in Schedules III, IV, and V shall be maintained either in a separate prescription file or in such form that they are readily retrievable from the other prescription records of the pharmacy. They will be deemed readily retrievable if, at the time they are initially filed, the face of the prescription is marked in red ink in the lower right corner with the letter "C" no less than one-inch high and filed in the usual consecutively numbered prescription file for non-controlled substances. However, if a pharmacy employs an electronic recordkeeping system for prescriptions which permits identification by prescription number and retrieval of original documents by prescriber's name, patient's name, drug dispensed, and date filled, then the requirement to mark the hard copy prescription with a red "C" is waived.

1913.9 All prescription orders shall be in compliance with requirements under this section, the Act and Title 21, CFR Part 1306, where applicable.

1913.10 There shall be maintained in each pharmacy a bound volume, which shall be

available for inspection by the Director, in which shall be recorded information required by federal or District of Columbia law or regulation concerning each sale of:

(a) Over-the-counter (OTC) Schedule V controlled substances;

(b) Hypodermic syringes, needles, or other medical devices which may be used in the administration of controlled substances;

(c) Gelatin capsules and glassine envelopes in quantities sufficient to indicate an intention to use such substances for the illegal distribution or dispensing of any controlled substance; and

(d) Diluents or adulterants, such as lactose or quinine, in quantities sufficient to indicate an intention to use such substances for the illegal distribution or dispensing of any controlled substance.

1913.11 A pharmacy shall maintain a patient record system in an automated data processing system or manual record system which shall provide for the immediate retrieval of patient information during the pharmacy's normal operating hours which may include:

(a) Full name of the patient for whom the drug is intended;

(b) Street address and telephone number of the patient;

(c) Patient's age or date of birth;

(d) Patient's gender, height and weight;

(e) A list of all prescription drug orders obtained by the patient at the pharmacy maintaining the patient record during the (5) years immediately preceding the most recent entry showing the name of the drug, prescription number, name and strength of the drug, the quantity and date received, and the name of the practitioner;

(f) The pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug;

(g) Patient allergies, drug reactions, current medications and relevant prior medications including non-prescription medications and relevant devices, or medication conditions which are communicated by the patient or the patient's agent; and

(h) Any other information which the pharmacist, in his or her professional judgment, deems appropriate.

1913.12 A patient record shall be maintained for a period of not less than five (5) years from the date of the last entry in the profile record. This record may be a hard copy or a computerized form.

1913.13 Prescription records, patient records, and any other individually identifiable health care information shall be maintained, used, and disclosed only in a manner that protects the integrity and confidentiality of the information, and that is in compliance with the requirements of HIPPA, and all applicable federal and District of Columbia laws and regulations.

1913.14 Authorized agents of the Director shall have immediate and unimpeded access to all pharmacy patient records and the pharmacist-in-charge shall be responsible for informing their superiors.

1914 COMPUTERIZED RECORDKEEPING

1914.1 A pharmacy may use an automated data processing system to meet the recordkeeping requirements under § 1913 of this Title if the system meets the requirements of this section.

1914.2 The automated data processing system shall have:

(a) Adequate security and systems safeguards designed to prevent and detect unauthorized access, modification, or manipulation of patient records. A pharmacy shall document any alterations in the prescription drug order, occurring after the prescription has been dispensed, and identify the pharmacist responsible for the alteration;

(b) The capability of producing:

(1) Readable required documentation and information on all original and refilled prescriptions through on-line retrieval, or, from the cathode ray tube (CRT), microfiche, microfilm, printout, or other method acceptable to the Board of Pharmacy; and

(2) A refill-by-refill audit trail for any specified strength and dosage form of any drug. The audit trail shall be by printout, and include the name of the prescribing practitioner, name and location of the patient, quantity dispensed on each refill, dispensing date of each refill, name or identification code of the pharmacist performing the final verification, and unique identifier of the prescription drug order.

(c) The capability to print all information entered into the system on paper within three (3) business days; and

(d) Adequate safeguards to ensure security and confidentiality of patient records pursuant to the applicable federal and District of Columbia laws and regulations.

1914.3 A pharmacist shall be responsible for the completeness and accuracy of the information he or she enters into the automated data processing system.

1914.4 All entries made into the automated data processing system shall include the initials or identification code of the dispensing pharmacist responsible for the transaction giving rise to the entry.

1914.5 The pharmacist-in-charge shall maintain a record keeping system in which each pharmacist involved in dispensing shall sign a statement each day attesting to the fact that the prescription information entered into the computer that day has been reviewed and is correct as shown. The log book or file shall be maintained at the pharmacy for a period of five (5) years from the date of dispensing. Records which are more than two (2) years old may be stored offsite as long as they can be retrieved within three (3) business days of a request.

1914.6 Any facility maintaining centralized prescription records shall be capable of sending a requested printout to the Pharmacy within seventy-two (72) hours.

1914.7 The pharmacist-in-charge, Director of Pharmacy, or Responsible Nuclear Pharmacist, as applicable, shall develop and implement a policy and procedure manual for the operational aspects of the automated data processing system which shall:

(a) Identify the required output documentation stored and provided by the system;

(b) Identify the procedures for when the system is not operational;

(c) Outline the regular and routine backup file and file maintenance procedures;

(d) Outline the audit procedures;

(e) Identify personnel responsibilities; and

(f) Provide a quality assurance mechanism for data entry validation.

1914.8 A pharmacy shall maintain sufficient patient data and prescription drug order data, in hard copy format, to permit reconstruction of the data and proper dispensing of prescription orders, within two (2) hours of an unscheduled system interruption or malfunction of the automated data processing system.

1914.9 A pharmacy shall have an auxiliary system or procedures in place to ensure that all refills are authorized and that the maximum number of refills is not exceeded, if the

automated data processing system is inoperative for any reason. In the event the actual number of remaining authorized refills cannot be determined and the pharmacist is unable to contact the prescribing provider for a new prescription, the pharmacist may use his or her professional judgment to dispense not more than a seven (7) day supply to cover or prevent a medical emergency.

1914.10 The auxiliary system set forth in § 1914.9 shall be capable of meeting the requirements of this chapter and functioning in the place of the automated data processing system until the automated data processing system is again operational.

1914.11 All prescription drug order information shall be entered into the automated data processing system not more than ninety-six (96) hours after the automated data processing system is again operational.

1914.12 A pharmacy shall implement routine backup file and file maintenance procedures to prevent loss of patient data.

1914.13 A pharmacy shall notify the Board of Pharmacy of a permanent loss of prescription drug order information or patient information due to a system failure, not more than twenty-four hours (24) after the discovery.

1914.14 A pharmacy shall be responsible for continuity in the maintenance of prescription records if the relationship with its data processing services supplier terminates.

1914.15 A pharmacy using an automated data processing system shall comply with all applicable federal and District of Columbia laws and regulations.

1915 AUTOMATED MEDICATION DISPENSING SYSTEMS

1915.1 An automated medication dispensing system may be utilized in a licensed pharmacy or health care facility if the requirements of this section are being met.

1915.2 An automated medication dispensing system shall be used only in settings where there is an established program of pharmaceutical care that ensures prescription orders are reviewed by a pharmacist in accordance with established policies and procedures and good pharmacy practice.

1915.3 The recordkeeping requirements of this section may be met by maintaining the most recent two years of records on site and the remaining three years of records off site as long as the records can be retrieved within three (3) business days of a request.

1915.4 A pharmacy shall provide the Director written notice of the installation of an automated medication dispensing system prior to utilizing an automated medication dispensing system. The notice shall include:

(a) The name and address of the pharmacy;

(b) The location of the automated equipment;

(c) The identification of the responsible pharmacist; and

(d) The type of system, manufacturer's name, make, and model.

1915.5 An automated medication dispensing system shall have adequate security and procedures to:

(a) Prevent unauthorized access;

(b) Comply with federal and District of Columbia laws and regulations; and

(c) Maintain patient confidentiality.

1915.6 An automated medication dispensing system shall electronically record all transactions involving drugs stored in, removed, or dispensed from the system.

1915.7 The pharmacy, or provider pharmacy providing remote pharmacy services, shall:

(a) Maintain records regarding the automated medication dispensing system in a readily retrievable manner for at least five (5) years. The records shall include:

(1) Maintenance records and service logs;

(2) System failure reports;

(3) Accuracy audits and system performance audits;

(4) Copies of reports and analyses generated as part of the quality assurance program;

(5) Reports or databases related to level of access and changes in the level of access to the system; and

(6) Training records including the training content, date, and identity of those attending the training program.

(b) Maintain dispensing records for all prescription drugs or devices dispensed or distributed from the automated medication system for a period of five (5) years and shall include:

(1) Identity of the system accessed;

(2) Identification of the individual accessing the system;

(3) Date of transaction;

(4) Name, strength, dosage form, and quantity of drug accessed; and

(5) Name of the patient for whom the drug was accessed.

(c) Maintain stocking and removal records of all drugs stored in and removed from the system for a period of five (5) years, which shall include identification of the person stocking or removing drugs from the system and identification of the pharmacist who verified that the system was accurately filled;

(d) Maintain records, including records of drugs discarded through the use of a reverse distributor, of all drugs discarded as waste for a period of five (5) years, which shall include identification of the person discarding the drugs and the identification of the pharmacist who verified that the drugs were properly discarded in accordance with federal and District law and regulations;

(e) Ensure that the automated medication dispensing system maintains the integrity of the information in the system and protects patient confidentiality;

(f) Ensure that a comprehensive program of quality assurance for the automated medication dispensing system is in place;

(g) Ensure that the system complies with this chapter;

(h) Maintain policies and procedures related to:

(1) The operation of the system;

(2) Training of personnel using the system; and

(3) Operations during system down time;

(i) Establish a process to:

(1) Ensure the security of the system;

(2) Account for medication added to and removed from the system; and

(3) Minimize the potential for misidentification of medications, dosages, and dosage forms by those accessing the automated medication system; and

(j) Ensure that authorized individuals working with the automated medication dispensing system receive initial and annual training regarding:

(1) The capabilities and limitations of the system;

(2) The operation of the system; and

(3) Procedures for system downtime.

1915.8 The records which are required to be maintained pursuant to § 1915.7 shall be stored on site where the automated medication dispensing system is located.

1915.9 The Director of Pharmacy or pharmacist-in-charge shall:

(a) Control access to the automated medication dispensing system;

(b) Designate in writing the individuals who are authorized to access the system;

(c) Establish criteria and a process for determining which drugs may be stored in the automated medication system;

(d) Develop policies and procedures regarding the automated medication system; and

(e) Be responsible for all pharmacy operations involving the automated medication dispensing system.

1915.10 Access to the automated medication dispensing system shall be limited to individuals that have completed documented training concerning the automated pharmacy system and who are one of the following:

(a) Licensed pharmacist;

(b) Qualified pharmacy personnel under a licensed pharmacist's supervision; or

(c) Individuals permitted by law to administer medication.

1915.11 Where a centralized automated medication dispensing system is being used, a licensed pharmacist shall perform a final check of each medication that is removed from the system prior to distribution or dispensing, unless:

(a) A licensed pharmacist utilizing a centralized automated medication dispensing system distributes patient specific medications within the licensed health care facility and the medication is distributed for subsequent administration by a health care professional permitted by law to administer medication; or

(b) A licensed pharmacist performs a daily quality assurance check of the integrity of the system that includes random sampling of the output.

1915.12 Where a decentralized automated medication dispensing system is being used:

(a) A licensed pharmacist shall perform a review of each order for medication before the medication is removed from the system, except if the order is for a starter dose; and

(b) A licensed pharmacist shall perform a review of each order for a starter dose within twenty-four (24) hours of removal of the starter does from the remote or decentralized automated medication system, if the patient is still under the care of the facility when the review is to be performed.

1915.13 Only a licensed pharmacist may fill an automated medication dispensing system, unless otherwise specifically permitted by this section.

1915.14 Automated medication dispensing systems that possess sufficient safeguards to ensure accuracy of the replenishment may be filled by:

(a) Authorized personnel pursuant to § 1915.9(b), supervised by a licensed pharmacist with a pharmacist performing the final verification; or

(b) Health care professionals licensed under the Act, and authorized to access an automated medication dispensing system due to the health care professionals' privileges to administer medication.

1915.15 Only a licensed pharmacist may return medication to the automated medication dispensing system, unless otherwise specifically permitted by this section.

1915.16 Automated medication dispensing systems that possess sufficient safeguards to ensure accuracy of the replenishment may allow for medication to be returned to those systems by:

(a) Authorized personnel pursuant to § 1915.9(b), supervised by a licensed pharmacist; or

(b) Health care professionals licensed under the Act, and authorized to access an automated medication dispensing system due to the health care professionals' privileges to administer medication.

1915.17 Medication which is returned to an automated medication dispensing system may be used for subsequent administration provided that:

(a) The drugs are in sealed, tamper evident packaging which has not been opened;

(b) The medication is in an unadulterated form;

(c) If in a unit of use package, the medication is in the intact package that the medication was in when initially removed from the system;

(d) The return of medication is documented within the system or in other records maintained by a licensed pharmacist; and

(e) The return of medication is conducted in accordance with written procedures.

1915.18 Drugs for use in an automated medication dispensing system shall be packaged in the original manufacturer's container or be prepackaged and labeled in compliance with the requirements of this chapter, and applicable federal and District laws and regulations.

1915.19 Controlled dangerous substances shall only be dispensed and distributed in accordance with applicable federal and District of Columbia laws and regulations.

1916 REMOTE AUTOMATED PHARMACY SERVICES

1916.1 The purpose of this section is to provide standards for the provision of remote pharmacy services by a provider pharmacy in a facility that is not at the same location as the provider pharmacy through an automated pharmacy system.

1916.2 A provider pharmacy may provide remote pharmacy services directly or through the use of a Board-approved subcontractor using an automated pharmacy system to a health care facility or other appropriate facility located in the District of Columbia if:

(a) The provider pharmacy submits an application to the Director for permission to provide remote pharmacy services using an automated medication dispensing system. The application shall include:

(1) The name, address, and license number of the provider pharmacy;

(2) The name and address of the facility where the remote pharmacy services will be provided;

(3) The name and address of the subcontractor who will provide after-hours remote pharmacy services, if applicable;

(4) An affidavit with the notarized signatures of the pharmacist-in-charge, and the medical director or the person responsible for the on-site operation of the facility affirming that the provider pharmacy and the facility have entered into a written agreement outlining the responsibilities of each party in complying with this chapter and the applicable federal and District laws and regulations; and

(5) Documentation that the automated medication dispensing system is located where medications are administered by authorized health care professions.

(b) The Director approves the application. Upon approval of the application, the provider pharmacy will be sent a certificate which must be displayed at the remote site.

1916.3 A provider pharmacy may only utilize a subcontractor for the provision of after-hours and weekend remote pharmacy services, or in the case of an emergency situation caused by forces majeure, i.e. acts of God.

1916.4 A provider pharmacy shall notify the Director in writing within ten (10) days of a change of location, discontinuance of service, or closure of a remote site or remote pharmacy service.

1916.5 The pharmacist-in-charge of the provider pharmacy is responsible for all pharmacy operations involving the automated pharmacy system located at the remote site including supervision of the automated pharmacy system and compliance with this section.

1916.6 The following duties shall be performed only by a licensed pharmacist at the provider pharmacy:

(a) Receiving an oral, facsimile, or electronic prescription drug order;

(b) Interpreting the prescription drug order;

(c) Verifying the accuracy of the prescription data entry;

(d) Selecting the drug product;

(e) Interpreting the patient's medication records and conducting a drug regimen review;

(f) Authorizing the telepharmacy system to print a prescription label at the remote site; and

(g) Performing the final check of the dispensed prescription to ensure that the prescription drug order has been dispensed accurately as prescribed. The final check shall be accomplished through a visual check using electronic methods.

1916.7 Patient counseling of an inpatient of a health care facility may be performed by either a pharmacist or a licensed health care professional authorized to administer drugs.

1916.8 Drugs shall only be dispensed at a remote site through an automated prescription medication dispensing system if:

(a) An original prescription drug order has been received, or reviewed electronically, by a pharmacist at the provider pharmacy;

(b) A pharmacist at the provider pharmacy has approved the release of the initial dose of a prescription drug order; and

(c) A pharmacist at the provider pharmacy has conducted a drug regimen review prior to releasing a prescription drug order to the automated pharmacy system.

1916.9 Non-sterile drugs which require reconstitution through the addition of a specified amount of water may be dispensed by the remote site only if a registered pharmacy technician or an authorized licensed healthcare provider reconstitutes the product.

1916.10 Subsequent doses from an approved prescription drug order may be removed from the automated medication system by, authorized personnel, after the initial approval. Any change made in the prescription drug order shall require a new approval by a pharmacist to release the drug.

1916.11 A provider pharmacy shall only store drugs at a remote site within an automated medication dispensing system that is locked by key or combination so as to prevent access by unauthorized personnel.

1916.12 A pharmacist from the provider pharmacy shall be accessible at all times to respond to a patient's or other health professional's questions and needs pertaining to drugs dispensed through an automated medication dispensing system at a remote site. The access may be by telephone or through a twenty-four (24) hour pager service.

1916.13 The provider pharmacy shall be responsible for ensuring that the requirements set forth under §§ 1914 and 1915 of this Title are met, and for maintaining all required records.

1916.14 The pharmacist-in-charge of the provider pharmacy shall be responsible for ensuring that the remote site and automated medication dispensing system comply with all applicable federal and District laws and regulations.

1916.15 Nothing in this section shall be construed to permit a pharmacy, or provider pharmacy, located within the District of Columbia to provide remote pharmacy services to a facility or individual located outside of the District of Columbia without legal authorization under the laws of the recipient state or jurisdiction.

A new section 1917 is added to read as follows:

1917 TELEPHARMACY SERVICES

1917.1 The purpose of this section is to provide standards for the provision of remote pharmacy services by a provider pharmacy in a facility that is not at the same location as the provider pharmacy through a telepharmacy system.

1917.2 Telepharmacy systems may only be used in institutional settings.

1917.3 A provider pharmacy may provide remote pharmacy services directly, or through the use of a Director-approved subcontractor, using a telepharmacy system to a health care facility or other appropriate facility located in the District of Columbia if:

(a) The provider pharmacy submits an application to the Director for permission to provide remote pharmacy services using a telepharmacy system. The application shall include:

(1) The name, address, and license number of the provider pharmacy;

(2) The name and address of the facility where the remote pharmacy services will be provided;

(3) The name and address of the subcontractor who will provide after-hours remote pharmacy services; and

(4) An affidavit with the notarized signatures of the pharmacist-in-charge or Director or Pharmacy, and the medical director or the person responsible for the on-site operation of the facility affirming that the provider pharmacy and the facility have entered into a written agreement outlining the responsibilities of each party in complying with this chapter and the applicable federal and District laws and regulations.

(b) The Director approves the application. Upon approval of the application, the provider pharmacy will be sent a certificate which must be displayed at the remote site.

1917.4 A provider pharmacy may only utilize a subcontractor for the provision of after-hours and weekend remote pharmacy services; or as emergency staffing where the President of the United States or the Mayor has declared a disaster or bio-terrorism related event in the District of Columbia.

1917.5 A provider pharmacy and the facility shall notify the Director in writing within ten (10) days of a change of location, discontinuance of service, or closure of a remote

site or remote pharmacy service.

1917.6 The pharmacist-in-charge or director of pharmacy, of the provider pharmacy is responsible for all pharmacy operations involving the telepharmacy system located at the remote site including supervision of the telepharmacy system and compliance with this section.

1917.7 The following duties shall be performed only by a licensed pharmacist at the provider pharmacy:

(a) Receiving an oral prescription drug order;

(b) Interpreting the prescription drug order;

(c) Verifying the accuracy of the prescription data entry;

(d) Interpreting the patient's medication records and conducting a drug regimen review;

(e) Authorizing the telepharmacy system to print a prescription label at the remote site;

(f) Performing the final check of the dispensed prescription to ensure that the prescription drug order has been dispensed accurately as prescribed. The final check shall be accomplished through a visual check using electronic methods; and

(g) Counseling the patient. This counseling may be performed using electronic methods such as telephone, email, video conferencing, and webcam.

1917.8 Nonsterile drugs which require reconstitution through the addition of a specified amount of water may be dispensed by the remote site only if a registered pharmacy technician or an authorized licensed healthcare provider reconstitutes the product.

1917.9 Drugs shall only be dispensed at a remote site through a telepharmacy system if:

(a) An original prescription drug order has been received, or reviewed electronically, by a pharmacist at the provider pharmacy;

(b) A pharmacist at the provider pharmacy has approved the release of the initial dose of a prescription drug order;

(c) A pharmacist at the provider pharmacy has conducted a drug regimen review prior to releasing a prescription drug order to the telepharmacy system; and

(d) A pharmacist is able to electronically supervise the telepharmacy system and the dispensing of the prescription drug order.

1917.10 Drugs may be dispensed by the provider pharmacy through a telepharmacy system at a remote site only in unit-of-use or unit dose containers that are:

(a) Prepackaged in suitable containers at the provider pharmacy and appropriately labeled as required under this Title; or

(b) In original manufacturer's or distributor's containers.

1917.11 A provider pharmacy shall only store drugs at a remote site within an area that is locked by key or combination so as to prevent access by unauthorized personnel.

1917.12 A pharmacist from the provider pharmacy shall be accessible at all times to respond to a patient's or other health professional's questions and needs pertaining to drugs dispensed through a telepharmacy system at a remote site. The access may be by telephone or through a twenty-four (24) hour pager service.

1917.13 The provider pharmacy shall be responsible for ensuring that the requirements set forth under §§ 1913 and 1914 of this Title are met and for maintaining all required records.

1917.14 The pharmacist-in-charge or Director of Pharmacy of the provider pharmacy shall be responsible for ensuring that the remote site and telepharmacy system comply with all applicable federal and District laws and regulations.

1917.15 Nothing in this section shall be construed to permit a pharmacy, or provider pharmacy, located within the District of Columbia to provide remote pharmacy services to a facility or individual located outside of the District of Columbia without legal authorization under the laws of the recipient state or jurisdiction.

Sections 1918 to 1923 are amended to read as follows:

1918 PROSPECTIVE DRUG REGIMEN REVIEW

1918.1 For purposes of promoting therapeutic appropriateness, a pharmacist shall, prior to or at the time of dispensing a prescription drug order, review the patient's medication record and each prescription drug order presented for dispensing. The review shall include screening for the following, if available:

(a) Over-utilization or under-utilization;

(b) Therapeutic duplication;

(c) Drug-disease contra-indications;

(d) Drug-drug interactions;

(e) Incorrect drug dosage or duration of drug treatment;

(f) Drug-allergy interactions;

(g) Reasonable dose and route of administration;

(h) Clinical abuse/misuse;

(i) Proprietary or over-the-counter drugs;

(j) Natural or herbal products; and

(k) Homeopathic products.

1918.2 Upon identifying any of the above, the pharmacist shall take appropriate steps to avoid or resolve any problem or potential problem including consultation with the practitioner. The pharmacist shall document such occurrences.

1918.3 The pharmacy must maintain the patient profile in a readily retrievable manner meeting the requirements of § 1913.11 of this Chapter.

1919 PATIENT COUNSELING

1919.1 Following review of a patient's medical record and prior to dispensing a drug or medical device, a pharmacist shall make a verbal offer to counsel, or his designee shall notify the patient or the patient's agent of the opportunity to receive an oral consultation from the pharmacist:

(a) Whenever a prescription drug or device has not previously been dispensed to a patient;

(b) Whenever a prescription drug or device has not previously been dispensed to a patient in the same dosage form, strength, or with the same written directions;

(c) Once yearly on maintenance medications; or

(d) Whenever the pharmacist deems it warranted in the exercise of his or her professional judgment.

1919.2 The pharmacy shall post a sign in a conspicuous manner informing patients of their right to receive an oral consultation from the pharmacist regarding their prescriptions.

1919.3 The consultation shall be face to face, whenever practicable, or by telephone and shall include appropriate elements of patient counseling which may include the following:

(a) The name and description of the drug or device;

(b) The dosage form, dosage, route of administration, and duration of drug therapy;

(c) Intended use of the drug or device and expected action;

(d) Special directions and precautions for preparation, administration, and use by the patient;

(e) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;

(f) Techniques for self-monitoring of drug therapy;

(g) Proper storage;

(h) Prescription refill information;

(i) Action to be taken in the event of a missed dose; and

(j) Pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient, drug, or device.

1919.4 The consultation shall be reinforced with the provision of written information which may include:

(a) Information leaflets:

(b) Pictogram labels; or

(c) Video programs.

1919.5 When the patient or patient's agent is not present, as in the case of prescription deliveries, the pharmacist shall ensure that the patient receives written notice:

(a) Of his or her right to request consultation; and

(b) A telephone number from which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's record.

1919.6 Only a pharmacist may counsel a patient or the patient's agent and answer questions concerning prescription drugs or devices.

1919.7 A pharmacist shall assess to the best of his or her ability that the patient or agent understands the counseling information provided.

1919.8 A pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses consultation. The pharmacist shall document such refusal for consultation.

1919.9 A pharmacist shall not be required to counsel an inpatient of a health care facility, where other licensed health care professionals are authorized to administer drugs, except upon request.

1920 PHARMACIST-IN-CHARGE

1920.1 A retail/community pharmacy, special or limited use pharmacy, or non-resident pharmacy shall be managed by a pharmacist (hereafter referred to as "Pharmacist-in-charge"). The pharmacist-in-charge shall be licensed to practice pharmacy in the District of Columbia, except that the pharmacist-in-charge of a non-resident pharmacy shall be licensed in the state in which the pharmacy is located.

1920.2 A pharmacist may not serve as a pharmacist-in-charge unless he is physically present in the pharmacy a sufficient amount of time to provide supervision and control. A pharmacist may not serve as a pharmacist-in-charge for more than one (1) pharmacy at a time except upon obtaining written permission from the Director.

1920.3 In addition to any other responsibilities set forth under this Title, the pharmacist-in-charge or proprietor of a pharmacy shall have the following responsibilities:

(a) Ensuring that quality assurance programs are in place for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems. Quality assurance programs shall be designed to prevent and detect drug diversion;

(b) Developing or adopting, implementing, and maintaining a training manual and program for the training of all individuals employed in the pharmacy who are legally authorized to assist in the practice of pharmacy. The pharmacist-in-charge shall be responsible for supervising the training program;

(c) Developing or ensuring the establishment of policies and procedures for the procurement, storage, security, and disposition of drugs and devices;

(d) Developing or ensuring the establishment of policies and procedures for the provision of pharmacy services;

(e) Ensuring that the automated pharmacy system is in good working order and accurately dispenses the correct strength, dosage form, and quantity of the drug prescribed while maintaining appropriate recordkeeping and security safeguards;

(f) Implementing an ongoing quality assurance program that monitors performance of the automated pharmacy system, which is evidenced by written policies and procedures;

(g) Ensuring that all pharmacists employed at the pharmacy are currently licensed in the District of Columbia, or if it is a non-resident pharmacy, in the state in which the pharmacy is located;

(h) Ensuring that all pharmacy interns employed at the pharmacy are currently registered in the District of Columbia;

(i) Ensuring the making or filing any reports required by federal or District of Columbia laws or regulations, which shall include but not be limited to, notifying the Director of the occurrence of any of the following:

(1) Permanent closing;

(2) Change of proprietorship, management, location, or pharmacist-in-charge;

(3) Any theft or loss of prescription drugs or medical devices;

(4) Conviction of any employee of any federal, state, or District of Columbia drug laws;

(5) Disasters, accidents, or any theft, destruction, or loss of records required to be maintained by federal or District of Columbia law or regulation;

(6) Occurrences of significant adverse drug reactions;

(7) Illegal use or disclosure of protected patient health information;

(j) Developing or ensuring the establishment of policies and procedures for preventing the illegal use or disclosure of protected health information, or verifying the existences thereof and ensuring that all employees of the pharmacy read, sign, and comply with the established polices and procedures; and

(k) Developing or ensuring the establishment of a procedure for proper management of drug recalls which may include, where appropriate, contacting patients to whom the recalled drug product(s) have been dispensed.

1920.4 The pharmacist-in-charge may be assisted by a sufficient number of pharmacists, pharmacy interns, and pharmacy technicians as may be required to competently and safely provide pharmacy services.

1920.5 The pharmacist-in-charge or proprietor of a pharmacy shall assure the development and implementation of written policies and procedures to specify the duties to be performed by pharmacy interns and pharmacy technicians. The duties and responsibilities of these personnel shall be consistent with their training and experience. These policies and procedures shall, at a minimum:

(a) Specify that pharmacy interns and pharmacy technicians are to be personally and directly supervised by a pharmacist stationed within the same work area who has the ability to control and who is responsible for the activities of the pharmacy interns and pharmacy technicians; and

(b) Specify that pharmacy interns and pharmacy technicians shall not be assigned duties that may be performed only by a pharmacist, which shall include but not be limited to:

(1) Drug utilization review;

(2) Clinical conflict resolution;

(3) Prescriber contact concerning prescription drug order clarification;

(4) Patient counseling on prescription, over-the-counter, and herbal products;

(5) Dispensing process validation;

(6) Receiving new oral prescription drug orders, or refill authorizations;

(7) Prescription transfers; and

(8) Independent compounding.

1921 INSTITUTIONAL PHARMACIES

1921.1 An institutional pharmacy shall be managed by a pharmacist (hereafter referred to as "Director of Pharmacy ") who is licensed to practice pharmacy in the

District of Columbia.

1921.2 The Director of Pharmacy shall be a full-time employee of the institutional facility in which the institutional pharmacy is located, except that the Director of Pharmacy may be a part-time employee when the pharmacy department or service is not located on site and a formal agreement exists for the provision of pharmaceutical services to the institution.

1921.3 The recordkeeping requirements of this section may be met by maintaining the most recent two years of records on site and the remaining three years of records off site as long as the records can be retrieved within three (3) business days of a request.

1921.4 The Director of Pharmacy shall be responsible for, at a minimum, the following:

(a) Developing or ensuring that the institutional pharmacy meets all requirements set forth under applicable federal and District of Columbia laws and regulations;

(b) Developing or adopting, and maintaining, and making available written policies and procedures that delineate the operation and activities of the provision of pharmacy services for the institution that ensure compliance with all applicable federal and District of Columbia laws and regulations;

(c) Ensuring that the pharmacy maintains and makes available a sufficient inventory of antidotes and other emergency drugs, both in the pharmacy and in patient care areas, as well as current antidote information, telephone numbers of regional poison control centers, and other emergency assistance organizations, and other materials and information as may be deemed necessary by the appropriate committee of the institutional facility, if any;

(d) Ensuring the provision of the appropriate level of pharmaceutical care services to patients of the institutional facility;

(e) Ensuring that drugs and devices are prepared for distribution safely, and accurately as prescribed;

(f) Ensuring a sufficient supply of drugs and devices to meet the needs of the patients of the institutional facility, and other appropriate equipment for the preparation thereof;

(g) Developing or ensuring the establishment of a system for the compounding, sterility assurance, quality assurance, and quality control of sterile pharmaceuticals compounded within the institutional pharmacy;

(h) Developing or ensuring the establishment of a system to assure that all pharmacy personnel responsible for compounding or for supervising the compounding of sterile pharmaceuticals within the pharmacy receive appropriate education and training and competency evaluation;

(i) Ensuring the provision of written guidelines and approval of the procedures to assure that all pharmaceutical requirements are met when any part of preparing, sterilizing, and labeling of sterile pharmaceuticals is not performed under direct pharmacy supervision;

(j) Developing or ensuring the establishment of a system for bulk compounding or batch preparation of drugs;

(k) Ensuring that the pharmacy maintains records of all transactions of the institutional pharmacy as may be required by applicable federal or District of Columbia law or regulations, and as may be necessary to maintain accurate control over and accountability for all pharmaceutical materials;

(l) Ensuring that the records in a data processing system are maintained in compliance with federal and District of Columbia laws and regulations;

(m) Ensuring the automated medication dispensing system is operated and maintained in compliance with federal and District of Columbia laws and regulations;

(n) Maintaining and making available metric-apothecaries weight and measure conversion tables and charts to applicable personnel;

(o) Maintaining and making available current reference materials on toxicology, pharmacology, bacteriology, sterilization, and disinfection;

(p) Preparation and sterilization of parenteral medications compounded within the institutional facility;

(q) Ensuring the education and training of nursing personnel concerning incompatibility and provision of proper incompatibility information when the admixture of parenteral products is not accomplished within the institutional pharmacy;

(r) Developing or ensuring the establishment and implementation of policies and procedures to ensure that discontinued and outdated drugs, and containers with worn, illegible, or missing labels are returned to the pharmacy for proper disposition, or that the Director of Pharmacy, or his or designees, make proper disposition of such drugs at the storage site;

(s) Developing or ensuring the establishment of and implementation of a recall procedure to assure the medical staff and the pharmacy staff that all drugs included on the recall are returned to the pharmacy for proper disposition;

(t) Ensuring documentation of suspected and reported adverse drug reactions to the prescriber;

(u) Ensuring the making and maintaining of reports of suspected reactions to the FDA, to the manufacturer, and to the United States Pharmacopoeia, and reporting of drug product defects accordingly; and

(v) Developing or ensuring the establishment of procedures for an ongoing quality assurance program of pharmaceutical services that includes a mechanism for reviewing and evaluating drug related patient care, as well as an appropriate response to findings.

1921.5 The Director of Pharmacy shall maintain the following records for a period of five (5) years:

(a) Physician's orders;

(b) Proofs of use of Schedule II controlled substances and any other drugs requested or required;

(c) Reports of suspected adverse drug reactions;

(d) Drug distribution records from night cabinets, automated medication dispensing systems, emergency kits, and similar systems;

(e) Inventories of the pharmacy;

(f) Inventories of controlled substances;

(g) Alcohol and flammable reports; and

(h) Any other records and reports as may be required by federal or District of Columbia law and regulations.

1921.6 In the event of an adverse drug reaction, an entry reflecting the reaction shall be made on the patient's pharmacy record.

1921.7 The Director of Pharmacy, at least once a month, shall inspect the pharmacy and all areas of the institution where drugs are stored or maintained, and make appropriate written records and notations of those inspections. An inspection shall verify that:

(a) Licensed pharmacists are responsible for all drugs dispensed and all prescription orders are checked by licensed pharmacists prior to leaving the pharmacy;

(b) Ancillary pharmacy personnel are properly directed and supervised;

(c) Drugs requiring special storage conditions are properly stored;

(d) Outdated drugs are retired from stock in the institutional pharmacy or the facility it serves;

(e) Controlled substances which have been distributed are properly and adequately documented and recorded by pharmacy personnel;

(f) Emergency medication kits are adequate and in proper supply both within the pharmacy and at outside storage locations; and

(g) Security and storage standards are met.

1921.8 The Director of Pharmacy shall be assisted by a sufficient number of additional licensed pharmacists as may be required to operate the institutional pharmacy competently, safely, and adequately to meet the needs of the patients of the facility.

1921.9 Trained technical and administrative personnel may be employed in a support capacity in institutional pharmacies, provided that the support activities are performed under the supervision of a pharmacist.

1921.10 Areas occupied by an institutional pharmacy shall be capable of being locked by key or combination to prevent access by unauthorized personnel.

1921.11 An institutional pharmacy, or any part thereof, shall be locked in the absences of personal and direct supervision by authorized personnel.

1921.12 The Director of Pharmacy shall designate in writing, by title and specific area, those persons who have access to particular areas within the pharmacy during non-business hours of the pharmacy.

1921.13 Authorized persons may have access to designated areas in the institutional pharmacy, and may remove drugs in compliance with the institution's established policies and procedures.

1921.14 Personnel authorized to have access to designated areas in the institutional pharmacy, shall receive thorough education and training in the proper methods of access, removal of drugs, and records and procedures required, prior to being permitted access to those areas of the pharmacy.

1921.15 The Director of Pharmacy or his or her designee shall administer the education and training required by § 1921.14 of this chapter.

1921.16 Removal of any drug from the pharmacy by an authorized person shall be recorded on a suitable form showing the patient's name, identification number, room number, name of the drug, strength, amount, date, time and the signature of the authorized person. The form shall be left with the container from which the drug was removed.

1921.17 During the times that an institutional pharmacy may be unattended by a licensed pharmacist, arrangements shall be made in advance by the Director of Pharmacy for provision of drugs to the licensed medical staff and other authorized personnel of the institutional facility by use of night cabinets, automated medication dispensing systems, telepharmacy systems, or by similar means, and in emergency circumstances, by access to a designated area of the pharmacy by persons authorized to handle, manage, or administer medication. A pharmacist shall be "on call" during all absences.

1921.18 If night cabinets are used, the following procedures shall be used:

(a) In the absence of a licensed pharmacist, drugs shall be stored in a locked cabinet or other enclosure constructed and located outside of the pharmacy area, to which only specifically authorized personnel may obtain access by key or combination, and which is sufficiently secure to deny access to unauthorized persons by force or otherwise;

(b) The Director of Pharmacy, in conjunction with the appropriate committee of the institutional facility, shall develop inventory listings of those drugs to be included in night cabinets and shall ensure that:

(1) All drugs available in the cabinet or similar container are properly stored and labeled; and

(2) Only prepackaged drugs are available, in amounts sufficient for immediate therapeutic requirements;

(3) Whenever access to the cabinet occurs, written practitioners' orders and proofs-of-use are provided to the pharmacist by the start of the business the following business day;

(4) All drugs therein are inventoried no less than once per week;

(5) A complete audit of all activity concerning the cabinet is conducted no less than once per month; and

(6) Written polices and procedures are established to implement the requirements of this subsection.

1921.19 Whenever any drug is not available from floor supplies, night cabinets, automated medication dispensing systems, telepharmacy systems, or by similar means, and the drug is required to treat the immediate needs of a patient whose health would otherwise be jeopardized, the drug may be obtained from the pharmacy in accordance with the following requirements:

(a) One (1) supervisory registered professional nurse, and only one (1), in any given eight (8) hour shift is responsible for obtaining drugs from the pharmacy. The responsible nurse shall be designated in writing by the appropriate committee of the institutional facility. The responsible nurse may, in times of emergency, delegate this duty to another licensed registered nurse;

(b) The responsible nurse shall, prior to being permitted to obtain access to the pharmacy, receive thorough education and training in the proper methods of access, removal of drugs, and records and procedures; and

(c) The Director of Pharmacy or his or her designee shall administer the education and training required in subsection (b) of this section.

1921.20 Removal of any drug from the pharmacy by an authorized nurse shall be recorded on a suitable form showing the patient's name, room number, name of the drug, strength, amount, date, time and the signature of the nurse. The form shall be left with the container from which the drug was removed.

1921.21 Investigational drugs shall be stored in and dispensed from the pharmacy only by a pharmacist. All information with respect to investigational drugs shall be maintained in the pharmacy.

1921.22 For an institutional facility that does not have an institutional pharmacy, drugs may be provided for use by authorized personnel by emergency kits located at the facility, provided the following requirements are met:

(a) The pharmacist-in-charge at the provider pharmacy shall determine, in consultation with the medical and nursing staff of the facility, which drugs and what quantity of those drugs should be included in the emergency kit and prepare the kit for use only by those persons licensed or authorized to administer drugs;

(b) The emergency kit shall contain the drugs required to meet the immediate therapeutic needs of patients and which are not available from any other authorized source in sufficient time to prevent risk of harm to patients by delay resulting from obtaining such drugs from such other sources;

(c) The emergency kit shall be sealed with a tamper evident seal, and stored in a secured area to prevent unauthorized access by force or otherwise, and to ensure a proper environment for preservation of the drugs inside the kit;

(d) The exterior of the emergency kit shall be labeled so as to clearly indicate that it is an emergency drug kit and that it is for use in emergencies only. The label shall contain a listing of the drugs contained in the kit, including the name, strength, quantity, and expiration date of the contents, and the name, address, and telephone number of the pharmacy who prepared the kit;

(e) All drugs contained in an emergency kit shall be labeled with the necessary information required by the medical staff of the institutional facility to prevent misunderstanding or risk of harm to the patients;

(f) Drugs shall be removed from emergency kits only pursuant to a valid written or verbal order by an authorized prescriber;

(g) Whenever an emergency kit is opened, the provider pharmacist shall be notified and the pharmacist shall restock and reseal the kit as soon as possible, but not more than seventy-two (72) hours after notification. In the event the kit is opened in an unauthorized manner, the pharmacist and other appropriate personnel of the facility shall be notified;

(h) The expiration date of an emergency kit shall be the earliest date of expiration of any drug supplied in the kit. Upon the occurrence of the expiration date, the provider pharmacist shall replace the expired drug; and

(i) The provider pharmacist shall, in conjunction with the medical staff of the institutional facility, develop and implement written policies and procedures to ensure compliance with the provisions of this subsection, and other applicable federal and District of Columbia laws and regulations.

1921.23 Drugs shall be dispensed from the institutional pharmacy only pursuant to the valid prescription order of an authorized practitioner.

1921.24 The Director of Pharmacy shall maintain a listing, including signatures, of those practitioners who are authorized to issue orders to the institutional pharmacy.

1921.25 Drugs brought into an institutional facility by a patient shall not be administered unless they can be identified by the pharmacist and the quantity and quality of the drug assured.

1921.26 The Director of Pharmacy shall develop or ensure the establishment and implementation of policies and procedures to ensure that if drugs brought into an institutional facility by a patient are not to be administered, that they are properly returned to an adult member of the patient's immediate family.

1921.27 Prescription drug orders for use by inpatients of the facility shall contain the following information:

(a) Patient name, identification number, and room number;

(b) Drug name;

(c) Drug strength;

(d) Directions for use and route of administration;

(e) Date and physician's signature, or signature of his or her authorized representative; and

(f) The words "Patient May Use Own Medications" when the prescription drug order is being written for drugs brought into the institution by the patient pursuant to § 1921.25.

1921.28 Prescription drug orders for use by outpatients shall, in addition to the information items required by § 1921.27, contain the patient's address, the facility's address, and DEA registration number, if applicable.

1921.29 Drugs dispensed for use by inpatients of an institutional facility, whereby the drug is not in the possession of the ultimate user prior to administration, shall be dispensed in appropriate containers and adequately labeled to meet the following requirements:

(a) The label of a single-unit package of an individual-dose or unit-dose system of packaging of drugs shall include:

(1) The generic, chemical, or brand name of the drug;

(2) The route of administration, if other than oral;

(3) The strength and volume, where appropriate,

(4) The control number or lot number, and expiration date;

(5) Identification of the repackager by name or by license number and shall be clearly distinguishable from the rest of the label; and

(6) Special storage conditions, if required.

(b) When a multiple-dose drug distribution system (i.e. blister cards) is utilized, including dispensing of single unit packages, the drugs shall be dispensed in a container to which is affixed a label containing the following information:

(1) Identification of the dispensing pharmacy;

(2) The patient's name;

(3) The date of dispensing;

(4) The generic, chemical, or brand name of the drug dispensed; and

(5) The drug strength.

1921.30 All drugs dispensed to inpatients for self administration, and all drugs dispensed to ambulatory or outpatients, shall contain a label affixed to the container indicating:

(a) The name and address of the pharmacy dispensing the drug;

(b) The name of the patient for whom the drug is prescribed; or, if the patient is an animal, the name of the owner, name of the animal, and the species of the animal;

(c) The name of the prescribing practitioner;

(d) Such directions as may be stated on the prescription drug order;

(e) The date of dispensing;

(f) Any cautions which may be required by federal or District of Columbia law,

(g) The serial number or prescription number of the prescription drug order;

(h) The name or initials of the dispensing pharmacist;

(i) The generic, chemical, or brand name of the drug dispensed;

(j) The strength, dosage, and quantity of the drug dispensed;

(k) The name of the manufacturer or distributor of the drug; and

(l) The expiration date.

1921.31 Pharmacies engaged in the practice of compounding and dispensing of parenteral solutions shall have a designated area for the preparation of sterile products for dispensing. Pharmacies shall ensure the following standards for this designated area:

(a) It shall meet standards for class 100 HEPA (high efficiency particulate air) filtered air such as a laminar air flow hood or clean room in accordance with Federal Standard 209(b), "Clean Room and Work Station Requirements", Controlled Environment, as approved by the Commission, Federal Supply Service, General Services Administration (41 CFR Part 5);

(b) It shall have cleanable surfaces, walls, and floors;

(c) It shall be ventilated in a manner not interfering with laminar air flow;

(d) The laminar air flow hood shall be certified annually in accordance with Federal Standard 209(b). Certification records shall be retained for a minimum of (5) years.

(e) The pharmacy shall be arranged in such a manner that the laminar-flow hood is located in an area which is exposed to minimal traffic flow, and is separate from any area used for bulk storage of items not related to the compounding of parenteral solutions. Items related to the compounding of parenteral solutions shall not obstruct the intake of the laminar flow hood. There shall be sufficient space, well separated from the laminar-flow hood area, for the storage of bulk materials, equipment, and waste.

(f) There shall be a sink with hot and cold running water located with the parenteral solution compounding area.

(g) There shall be a refrigerator or freezer of sufficient capacity to meet the storage requirements for all materials requiring refrigeration.

1921.32 In all pharmacies preparing parenteral cytotoxic agents, all compounding shall be conducted within a certified Class II Type A or Class II Type B vertical laminar air flow hood with bag-in, bag-out design. The pharmacy shall ensure that contaminated air plenume that are under positive air pressure are leak tight. The hood must be certified annually in accordance with National Sanitation Foundation Standard 49 or manufacturer's specifications. Certification records shall be retained for a minimum of five (5) years.

1921.33 In addition to existing labeling requirements, parenteral product labels shall include:

(a) Telephone number of the pharmacy;

(b) Name and concentrations of all ingredients contained in the parenteral product, including primary solution;

(c) Instructions for storage and handling; and

(d) A label for all cytotoxic agents which shall state: "Chemotherapy – Dispose of Properly".

1921.34 Pharmacies engaged in the practice of compounding and dispensing of parenteral solutions shall have on the premises, or readily accessible, a patient record for each patient being treated with parenteral therapy. In addition to existing recordkeeping requirements, the following records shall be maintained in the pharmacy:

(a) Records of the furnishing of all prescriptions and medical supplies;

(b) Progress notes documenting contact with the patient or physician relative to parenteral therapy; and

(c) Other data relevant to parenteral therapy.

1921.35 Gowns and gloves shall be worn when preparing cytotoxic agents.

1921.36 The Director of pharmacy shall ensure that all pharmacists engaging in compounding parenteral solutions have training or have demonstrated previous training in the safe handling and compounding of parenteral solutions, including cytotoxic agents.

1921.37 Pharmacies providing parenteral services shall have written policies and procedures for the disposal of infectious materials and materials containing cytotoxic residues.

(a) The procedures shall include cleanup of spills and shall conform with applicable District of Columbia and federal law and regulations.

(b) The pharmacy shall ensure the return of these materials or shall communicate the proper destruction of these materials to the caregiver.